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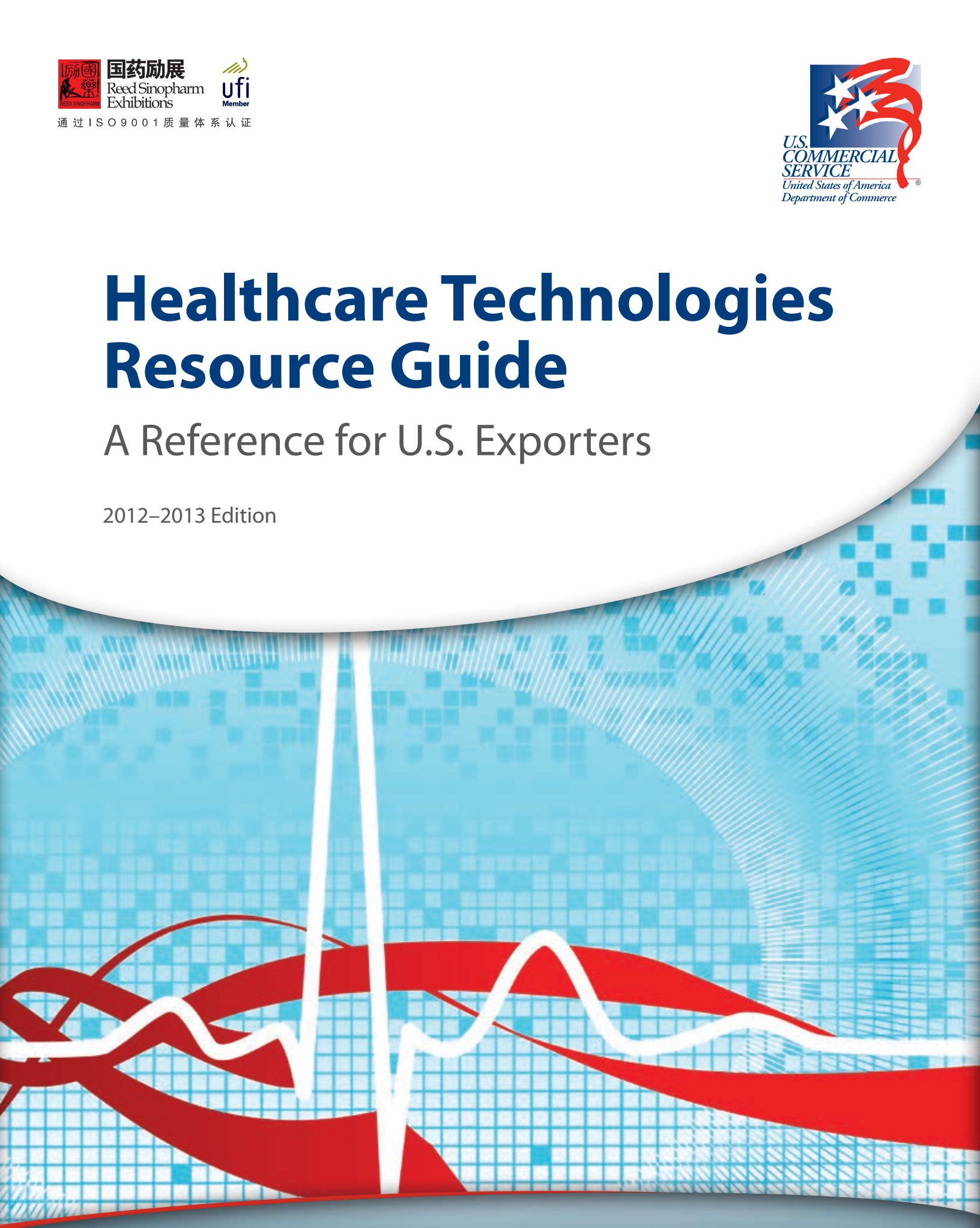
U.S. COMMERCIAL SERVICE
United States of America
Department of Commerce

Healthcare Technologies Resource Guide

A Reference for U.S. Exporters

2012–2013 Edition



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A Reference for U.S. Exporters

2012–2013 Edition

What Can the U.S. Commercial Service Do for You?

The U.S. Commercial Service (CS) is the export promotion arm of the U.S. Department of Commerce's International Trade Administration. Our global network of more than 1400 trade professionals is located throughout the United States and in U.S. Embassies and Consulates in more than 70 countries. Whether you're looking to make your first export sale or expand to additional markets, we offer the expertise you need to connect with lucrative opportunities and increase your bottom line.

The CS Healthcare Technologies Team works to address issues and trade opportunities specific to the strong and growing healthcare sector, and to ensure you have the information you need to grow your business. This resource guide is just one of the ways we can provide the information you need to set priorities and plan for business growth.

Our Services

With private and public spending on an upward trend in many countries, the U.S. Commercial Service has the knowledge and expertise to help you develop your international strategy.

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- Analyze market potential and foreign competitors
- Obtain useful information on best prospects, financing, laws, and cultural issues
- Conduct background checks on Potential buyers and distributors

Business Matchmaking

- Connect with pre-screened potential partners
- Promote your product or service to prospective buyers at trade events worldwide
- Meet with international industry and government decision makers in your target market(s)

Trade Counseling

- Develop effective market entry and sales strategies
- Understand export documentation requirements and import regulations of foreign markets
- Navigate U.S. government export controls, compliance, and trade financing options

Commercial Diplomacy

- Overcome trade obstacles to successfully enter international markets
- Benefit from coordinated U.S. government engagement with foreign governments to protect U.S. business interests
- Access U.S. government trade advocacy for your foreign government procurement bids

For more information on how CS can help your business increase its international sales, please contact your local CS office. (A list of offices appears at the back of this guide.)

We hope you find this guide helpful. Please do not hesitate to contact me directly if I can be of further assistance. We look forward to helping your business achieve its international goals!

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This Guide Supported in Part by

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The ratings and information in this guide represent the experiences and opinions of the commercial specialists responsible for the healthcare sector at U.S. embassies and consulates worldwide. Sub-sector categories are broad and may not all apply to all products within them. The client is encouraged to further research the market for a particular product or service. Additional barriers to entry (political turmoil, change in import duties, etc.) may be discovered once a market is further explored. Information in this guide is accurate as of publication date.

The U.S. Commercial Service has offices in more than 70 countries, and not all countries are represented in this guide. If you are interested in a market not listed here, please contact your nearest local CS office for more information. Contact information may be found in the back of this guide.

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Argentina

Summary

Overall healthcare expenditures in Argentina have traditionally accounted for approximately 7-10 percent of GDP, among the highest in the region. Imports in the overall healthcare sector have been estimated to account for around 70-75 percent of the total market. The United States continues to lead the Argentine import market of medical products and equipment, and currently holds 26 percent market share, particularly in higher-end technology products.

Argentina remains a key market for U.S. exports to Latin America. However, market challenges arising from slowing economic activity, inflationary pressures, and a host of import and foreign exchange restrictions imposed by the Argentine Government in late 2011 and early 2012 are expected to adversely affect imports and slow GDP growth in 2012 to 1-2 percent, down from about 8 percent in 2011.

Market Entry

Imports of medical products must be performed by an importer registered with the ANMAT (the Argentine equivalent to the FDA) as a frequent importer of medical equipment. Imported products appear under the name of the local registered importer who will fulfill the registration process as a representative of the U.S. company. Registration requirements vary according to product classification.

The Mercosur common external tariff (CET) applies to imports from countries outside the MERCOSUR area (Argentina, Brazil, Uruguay and Paraguay). The CET currently ranges from zero to 16 percent for medical products plus 0.5 percent in a statistics fee.

Current Market Trends

Imports of medical equipment, devices and instruments experienced an exceptional surge during 2011 and reached for approximately $778 million, with $198 million of this from the U.S. Import figures may remain sluggish during 2012 and it is unlikely that imports will grow so rapidly during 2012-2013.

Main Competitors

More than 2000 companies sell medical products and equipment in Argentina, of which 25 percent are manufacturers and 75 percent are importers. Brazil poses strong competition since imports enjoy a zero tariff under Mercosur. U.S., Japanese and European-made equipment is known for its high technology and precision, whereas Argentine equipment, although durable, is generally low-tech.

Statistics

Capital:	Buenos Aires
Population:	41 million
GDP:	USD $380 billion (2010)
Currency:	Peso (ARS)
Language:	Spanish

Contact

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Domestic production has been growing, although in general it is limited more to lower-middle range equipment and supplies, such as x-ray devices, peripheral equipment, illumination systems, furniture, operating tables, echographs and ECGs, monitors, oximeters, cobalt pumps, anesthesia equipment, sterilization equipment, basic lab equipment, instruments for arthroscopy, fixation instruments, instruments for video endoscopy surgery, wheelchairs, scales, etc

Current Demand

Medical products that cannot be manufactured locally present opportunities for U.S. exporters, particularly when offering high quality products at competitive prices. Niche opportunities for U.S. exports may include middle and higher-end equipment such as imaging diagnostics equipment, medical ultrasound equipment, and electrocardiograph equipment. There may be potential for implants, stents, cardiac valves, pacemakers, specialized disposables, molecular biology products, and diagnostic reagents.

Simpler technology is more easily financed and thus considered mass-market. In this competitive market the demand for these products is for the most part met. In any case, product potential should be determined on a case-by-case basis.

Barriers

Recent controls have made exporting goods from any country to Argentina more difficult as the Argentine government has imposed more processes that Argentine importers must complete in order to import goods. It is important for would-be exporters to Argentina to confirm that their Argentine customer has:

- Received the necessary permission to import;
- Received a non-automatic import license if required; and
- Obtained permission to purchase foreign exchange to pay for the import prior to shipping goods to Argentina.

For more information, please visit ***export.gov/argentina***.

Restrictions apply to imports of used medical equipment. Scarce financing available in the local market is an issue. However, two U.S. banks operate in Argentina to offer loans using Ex-Im Bank guarantees to importers of U.S. equipment.

Trade Events

Expomedical 2012

Buenos Aires • ***expomedical.com.ar***
Description: international exhibition of medical equipment, products, and supplies. Parallel seminars.

Available Market Research

- Medical Equipment, Instruments, and Supplies (2011)
- Medical Products Overview (2011)
- Dental Products Overview (2011)
- Electro Medical Equipment (2010)
- Imaging Diagnostics Equipment (2010)
- Orthopedic Equipment and Devices (2010)
- Clinical Laboratory Instruments and Reagents (2009)

Australia

Summary

The medical equipment industry sector has consistently provided good prospects for U.S. exporters. Australia is the eighth largest market for U.S. exporters of medical products. Approximately 80 percent of medical devices and diagnostics used in the market are imports. The three major suppliers are the United States, the European Union, and Japan. U.S. medical equipment is traditionally well received due to its perceived high quality. The market is sophisticated, mature, and quick to adopt new healthcare technologies. Importers seek to obtain cost-effective and innovative products that will improve patient outcomes and reduce healthcare costs.

Market Entry

Successful market entry strategies for Australia have three common elements: understanding the market, selecting the optimal partner, and providing ongoing support to that partner. It is important to gain an understanding of the Australian context for a product or service, its competitors, standards, regulations, sales channels, and applications. Success in the market will require appointing an Australian distributor or establishing a local subsidiary, and setting up a local sales presence. Typically, distributors for medical products will cover the entire country and some may also have a subsidiary office in New Zealand. Given the Australian continent is the same size as continental U.S., as well as its distance from other countries, local support and service is important. Most of the criteria American firms use to select distributors are applicable to Australia, with expectations adjusted to the scale of the market given the population of 22.6 million. Performing due diligence on potential local partners is just as important as in the United States.

Current Market Trends

Australia has a high per capita income and there is demand for a full range of medical equipment. The $5 billion market is price sensitive and competitive. Australia spends approximately 9.1 percent of its GDP on healthcare, which is similar to Italy, Spain, and Ireland but less than the United States. Australia's ageing population will significantly influence the demand for products and products that serve the ageing population are likely to experience growth.

The growth of chronic disease in Australia is similar to that in other developed nations. Australians increasingly suffer from asthma; cancer; diabetes; obesity; heart, stroke, and vascular disease; osteoarthritis, rheumatoid arthritis; and osteoporosis. Opportunities exist for technologies that avert or reduce disability because of these diseases.

Statistics

Capital:	Canberra
Population:	22.6 million
GDP:	USD 1.507 trillion
Currency:	Australian Dollar (AUD)
Language:	English

Contact

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Main Competitors

Imports supply approximately 80 percent of Australia's demand for medical equipment. Key suppliers include the United States, the European Union, Switzerland, and Japan. Many suppliers in the Australian industry are subsidiaries of overseas corporations. The major American medical companies represented in Australia (either through local representatives or subsidiary offices) include Bard, Baxter Healthcare, Boston Scientific, Cook Medical, Johnson & Johnson Medical, Medtronic, St. Jude Medical, Stryker, and Zimmer. U.S. companies may experience strong competition from American firms or multinationals already in the market.

Current Demand

Australia's high standard of medical practice and aging population underpin a continued demand for a range of sophisticated, high quality, and innovative medical equipment. Importers seek to source cost-effective and innovative products that will improve patient outcomes and reduce healthcares cists. Opportunities exist for products that provide a significant improvement in clinical outcomes, and product with clearly differentiated capabilities. There is also a growing demand for products that lead to faster patient recovery, reduce hospital and rehabilitation costs, and alleviate or manage disability and chronic pain.

Government healthcare policies and public health influence the volume and pricing of healthcare products and services. Both the public and private sectors provide healthcare in Australia. Federal and State government spending accounts for 70 percent of total healthcare expenditure. The non-governmental sector (individuals and private health insurance) funds are the remaining 30 percent. Approximately 45 percent of Australians have private health insurance.

Registration Process

The Therapeutic Goods Administration (TGA) regulates the medical equipment industry. Australia's regulatory framework is based on Global Harmonization Task Force (GHTF) and European Community guidelines. U.S. exporters must appoint an Australian representative/sponsor to obtain regulatory approval from the TGA. U.S.-manufactured medical devices require an EC Certificate from a European Union Notified Body. Alternatively, U.S. manufacturers can apply to the TGA for a Conformity Assessment Certificate.

Further information is available at ***tga.gov.au***.

Trade Events

AusBiotech 2012

October 30–November 2, 2012 • Melbourne Convention & Exhibition Centre • ***ausbiotechnc.org***

AusBiotech 2013

October 29–November 1, 2013 • Brisbane Convention & Exhibition Centre • ***ausbiotechnc.org***

Austria

Summary

Austria is a dynamic EU member country with an affluent population of 8.4 million German speakers. Austria's manageable size and stable business environment makes it an attractive market for U.S. exporters, as well as an attractive test market for U.S. firms with an eye toward expanding into neighboring Germany. Austria's historical and economic ties to the strong growth markets of Eastern and Southeastern Europe also make it a logical base for serving those markets. Currently, 333 U.S. firms have subsidiaries, affiliates, franchisees, and licensees in Austria, of which about 220 have regional responsibilities for Central European, Eastern European, or Balkan countries. U.S. products and services maintain a good reputation in Austria.

Austria is currently at the end of an extraordinarily strong immigration-induced population growth phase. Since the mid-eighties, the population has grown by half a million inhabitants to the current 8.4 million, due to the unexpectedly high level of immigration. Since 1996, this dramatic increase in immigration has stabilized. The population will therefore only grow slightly in the coming decades. The Central Austrian Statistics Office estimates that in the year 2020, approximately 8.7 million people will be living in Austria—a 9.5 percent increase from 1996 levels. In 2030, almost 9 million people are expected to live in Austria. This constitutes an increase of 6.9 percent compared to today's 2011 level. One of the major socio-political health challenges of the coming years is the rapid growth of the elderly population. The number of people over 60 years of age is currently approximately 1.8 million. This figure will have reached at least 2.8 million by the year 2030. At the present time, 20 percent of Austrians have reached retirement age, and it is projected that more than one third of the total population will be retired in the year 2021.

In 2010, Austrian imports of medical equipment were $1,865.3 million. We expect the 2011 imports, once published, to show an increase to $1,982.7 million. Total demand for medical devices in Austria added up to $1.2 billion, while exports of this equipment amounted to $1.8 billion. Austria is a transit-trade country with strong trade relationships with Central, Eastern and Southeastern Europe, as well as the Middle East. The re-exportation of products is quite common here; hence the volume of imports exceeds the total market. Taking into consideration these re-exports, imports are expected to increase at an average annual real growth rate of 3%. The Austrian size of the market for medical equipment should also increase about 3% annually over the next three years.

Statistics

Capital:	Vienna
Population:	8.4 million
GDP:	USD 419 billion (2011)
Currency:	Euro (€)
Language:	German

Contact

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Market Entry

U.S. firms should plan their market entry very carefully. Given its location in the center of Europe and the size of its market, small enough to allow a quick overview, Austria stands out as a desirable, affluent pilot market for advanced U.S. products. The best strategy is to screen potential distributors and select a qualified local distributor. Austrian distributors are usually knowledgeable and experienced. They regularly call on hospitals, clinics, laboratories, and medical doctors with practices. The majority of distributors are fluent in English. They are also knowledgeable about EU approval procedures and will obtain approval for U.S. suppliers if needed.

The successful U.S. supplier should discuss and agree on a marketing strategy with a prospective distributor. Once the agent or distributor is selected, it is preferable to maintain this relationship for a number of years. Abrupt changes in distribution patterns distract users from trusted suppliers and have been detrimental to U.S. suppliers who have taken such action in the past. It may take up to two years to introduce a new product due to the conservative and complex nature of the Austrian market.

The metric system of weights and measures is standard in Austria. The electric power supply is 230/400 volt, AC 50, 1 or 3 phases.

Current Market Trends

U.S.-made products that are on the cutting-edge will have great potential, as Austrians expect hospitals to have the latest technology. The trend, however, is to reduce the number of hospital beds and to close down some hospitals altogether. Therefore, American companies that are interested in hospital construction or in the sale of "routine" hospital equipment and supplies may find their prospects reduced over the next few years.

Projected growth rates for different imaging products vary considerably. The Austrian market for medical equipment is constantly evolving and utilizing increasingly sophisticated products.

Scanning units have benefited from technological improvements since their introduction about 30 years ago. Most suppliers now offer user-friendly features like image networking, which enable the user to digitally store and project high-quality images. These products should have very good prospects in the future.

Austria is an interesting market for echographic units. This ultrasound technique continues to gain popularity as the industry discovers new applications for it. Recent technological advances have enabled manufacturers to implement Doppler technology and sophisticated probes within their designs. Sales of conventional radiology apparatus (traditionally, the most popular type of equipment) have declined over the last several years. The recent ability to digitalize this out-dated equipment, however, has sparked new interest in traditional radiology. Interventionism radiology is the most recent development in the medical imagery field. A combination of radiology and surgery, interventionism radiology has resulted from advances in vascular radiology, digitalization techniques and catheter performance. It promises to have a strong future.

There is also an increasing demand for all kinds of in-vitro products in Austria.

Main Competitors

The great majority of medical equipment used in Austria is imported. U.S. manufacturers have seized a substantial share of the market and are now the second-largest supplier group, following German companies. German competition enjoys the advantages of geographic proximity, a common language, and products with the same standards, no exchange rate problems, and duty-free access through Austria's membership in the EU.

The Austrian market for medical equipment is sophisticated and well-served. Industry giants such as Siemens, Philips, Hitachi, and Toshiba are well entrenched. General Electric GmbH, Agilent Technologies Oesterreich GmbH, Nova Biomedical GesmbH, and Tyco Healthcare Austria GmbH are only a few of the Austrian subsidiaries of U.S. medical device suppliers. Against the heavy German competition in this market, American products can usually compete well on the basis of price and innovation.

Current Demand

The following high-quality products and devices are currently in demand in Austria:

- Nuclear medical instruments (nuclear magnetic resonance scanners)
- Diagnostic apparatus including cardiology instruments, echocardiography systems, advanced electrocardiograph equipment, monitoring systems,ultrasound equipment, gynecology and urology diagnostic systems, and endoscopes
- Scanners, computer tomography imaging systems, magnetic resonance imaging
- Dialysis equipment
- Pacemakers
- Sophisticated digitalized x-ray equipment
- Clinical laboratory equipment including blood cell counters, and blood gas analyzers
- In-vitro diagnostic products

The trend is moving toward miniaturization of electro-medical devices and nano-technology products.

Registration Process

All U.S. medical devices have to be marked with the mandatory CE (Conformité Européenne) conformity mark. With the CE marking on a product, the manufacturer ensures that the product conforms with the essential requirements of the applicable EC directives. Deviating from sector directives regulating other industrial goods, medical devices have to comply with "essential requirements" as described in Annex I of Directive 93/42/EEC. According to this, medical devices must not only be safe but must also function in a medical-technical way as described in the manufacturer's "intended purpose." Compliance with these requirements is proved within a certified quality management system according to EN ISO 13485.

Barriers

Austria is a highly developed open market with relatively liberal policies and sharp competition. The import climate is favorable towards U.S. products. American exporters, like domestic and European firms, are subject to packaging and other collection, recycling, and reprocessing laws. There are no significant trade barriers or limitations on U.S. medical devices.

Trade Events

At the present time, there is no general medical fair planned in Austria. Some smaller specialized medical exhibitions are organized in connection with medical conventions. The great majority of Austrian medical importers/distributors regularly attend the most important European medical fair:

MEDICA

November 14–17, 2012; November 20–23, 2013; November 12–15, 2014
Messe Duesseldorf GmbH, Duesseldorf, Germany

Considered the world's most important and largest international fair for medical equipment, the annual MEDICA draws 134,000 trade visitors from 85 countries. Over 5,200 distributors from 65 foreign countries are able to exhibit with over 2.8 million square feet of space in 17 halls.

Available Market Research

- Austria—Dental Industry Market Brief 2011
- Austria—In-Vitro Diagnostics 2011

Belgium

Summary

Belgium produces less than 10 percent of its overall needs for medical equipment. This leaves the market open for heavy competition among suppliers from the U.S., Germany, France and Great Britain.

The United States currently has a 20 percent share of total medical equipment imports into Belgium.

In 2010, the Belgian market for medical equipment was estimated at $4.2 billion and employed 18,000 people. Belgium imported approx. $1.9 billion worth of medical equipment from the U.S. in 2010. Over the past 5 years, this sector has seen an annual growth of approximately 3 to 4 percent. The Belgian Social Security System, which includes the Health Care System, is considered among the most extensive and efficient in Europe. It covers nearly 100 percent of the population of 10.5 million inhabitants. In 2010, total healthcare expenditure was estimated at $28 billion.

Market Entry

Belgium is an effective starting point for marketing medical equipment to the rest of Europe due to its geographical location, its effective healthcare system, and its relatively open attitude regarding procurement. Belgium is a distribution center for many multinationals: products are imported into Belgium and exported to other European countries.

In order to enter the medical equipment market in Belgium American suppliers should be familiar with the EU directives concerning the registration, marketing, and health/safety standards required throughout Europe as well as regulations specific to Belgium. It is therefore advisable to work with a local partner/ distributor.

The following EU directives were transposed into national law:

- Directive 90/385/EEC on active implantable medical devices
- Directive 93/42/EEC on medical devices
- ***ec.europa.eu/health/medical-devices/regulatory-framework***

Current Market Trends

Belgium's healthcare system is currently facing several challenges. Belgium's growing aging population and the higher health expectations will have an important impact on healthcare expenditures in the coming years. The GOB is therefore looking at various cost-saving measures. Thus, innovative technologies and equipment offering cost savings will have a strong market

Statistics

Capital:	Brussels
Population:	10,438,353
GDP:	USD 418.6 billion (2011)
Currency:	Euro (€)
Language:	Dutch, French, German

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potential. Orthopedic products, homecare products, obesity and diabetes products are as a consequence in high demand. Furthermore, there is a trend towards miniaturization of medical devices allowing more minimally-invasive and non-invasive procedures. Medical software, telemedicine and e-health are also sectors with a strong market potential.

Main Competitors

Belgium has approximately 800 companies manufacturing or distributing medical products. The majority of these firms are small or medium-sized, employing an average of 20 to 50 people. Belgian suppliers do well in niche markets, including diagnostic imaging, cancer diagnosis, and teleradiology.

Belgium is home to many subsidiaries of American companies such as GE Medical Systems, 3M, Abbott Vascular, Baxter, Johnson & Johnson medical, Medtronic, Becton Dickinson, Boston Scientific,

Cyberonics and St. Jude Medical. Siemens and Philips also have a strong presence in Belgium.

Current Demand

Best prospects:

- Innovative technologies
- Minimally invasive and non-invasive equipment
- User-friendly home care products
- E-Health
- Telemetry
- Consumables
- Orthopedic products
- Implantable products.

Registration Process

The distribution of medical devices is regulated by Belgian law. Distributors of Medical devices including active implantable devices should notify the Federal Agency for Medicines and Health Products. For more information, please visit ***fagg-afmps.be/en***.

Medical devices must bear the CE marking for conformity when marketed. Custom made implantable and non-implantable devices and devices for clinical investigation do not require CE marking. If a notified body has been involved in verifying the procedure of conformity, the CE marking must be accompanied by a four-figure number indicating the notified body. For more information, please visit ***export.gov/cemark***.

Barriers

There are no significant barriers on U.S. medical devices.

Trade Events

Healthcare

October 2014 • Brussels, Belgium • ***health-care.be***
Trade show for home healthcare products.

Brazil

Summary

Brazil is the largest medical equipment market in South America. It may account for approximately U$ 8 billion in sales in 2013. The total market for medical equipment in Brazil should continue to expand approximately 15% through 2012. Brazil is both a major medical equipment producer and importer. Imports of medical products increased 15% in the first months of 2012.

The United States accounts for approximately 30% of the import market, with U.S. sales mainly going through local agents, distributors and importers who sell to hospitals and clinics. The market for electro medicine equipment is around US$260 million, which represents approximately 50% of total sales in Latin America.

Market Entry

For medical products, it is necessary to have a local agent or distributor to import products from manufacturers. Because of regional economic disparities, varying states of infrastructure, and a host of other issues, it is often difficult to find one distributor that has complete national coverage. Main cities are São Paulo, Rio de Janeiro, Belo Horizonte, Brasília, Porto Alegre, Salvador, Recife and Curitiba.

Either setting up a company in Brazil or acquiring an existing entity is an investment option for Brazil. Setting up new companies is relatively complex, although the Ministry of Development has signaled a desire to simplify the process.

Companies are also joint venturing with Brazilian industries for final assembling and packaging of products. This process reduces import duties and documentations that are required for finished goods.

Current Market Trends

Brazil's recently strengthened currency has meant that private and public hospitals have greater purchasing power, and with continued expansion of Brazil's private health care sector, the market should grow. New opportunities for US exporters abound, particularly for:

- Clinical Chemistry, Biomedical and advanced medical devices—high demand for new technologies
- Laboratory equipment—investments in R&D, including some duties and registration exemptions
- Disposables and surgical—high consume from private and public hospitals
- Diagnostic devices and monitoring equipment—high demand for innovative products

Statistics

Capital:	Brasília
Population:	192,000,000
GDP:	USD 2.367 trillion
Currency:	Real
Language:	Portuguese

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to replace bigger and more expensive equipment

- Orthopedics and Implants—high demand of imported products, despite higher sanitary requirements
- Health IT—demand in hospitals, including education and second opinion programs
- Dental—Brazil has one of the highest number of dentists in the world
- Drugs, Pharmaceuticals and Nutrition Supplements—high dependency on imported products. New rules to facilitate imports of supplements. High demand for modern life products.

Main Competitors

There are few high-quality Brazilian manufacturers of advanced medical products so Brazil's reliance on imports should continue for some time. Local buyers view US and other foreign products (mainly Canadian and European) as having comparable quality and reliability. Thus, financing terms often become the differentiating criteria in making a sale.

Current Demand

An interesting trend in Brazil is the growing market for home health care products, which has increased dramatically in recent years. Brazil has approximately 150 home health care companies compared to approximately 1,440 in the US. In Brazil, these companies are increasingly viewed as good ways to cut hospitalization costs while offering better services for patients. Brazilian health insurance companies are responsible for paying 99% of the costs related to home care treatment, and as such, the U.S. Commercial Service sees the market for home health care products growing dramatically during the coming years. Brazil's Regional Nursing Council is currently developing procedures on how to regulate this market, including standards for health professionals.

In addition to the attractive size of the Brazilian medical market, US exporters should consider the opportunities offered by Mercosur, and use Brazil as a "spring board" for export into Argentina, Uruguay and Paraguay. Since compulsory product registration before sale is required for all of Mercosur countries, US exporters should consult a local lawyer/consultant before signing a contract with any agent/distributor.

Barriers

Medical products in Brazil are highly regulated by Anvisa, the Brazilian counterpart of FDA. All products must be registered or be notified in order to be commercialized. For products with higher grade risk, it may be necessary to have additional local certifications, international market data and even inspections in manufacturing plants.

Import system is very complex and can add up to 100% fees over products. For a more detailed explanation of this system please visit ***focusbrazil.org.br/ccg/PDFs/chapter5_traderegulations.pdf***.

Trade Events

Hospitalar

May 21–24, 2013 • São Paulo, Brazil • ***hospitalar.com***

This is the largest medical event in Latin America and one of the best opportunities to U.S. firms that are looking for business partnership in Brazil. Hospitalar is focused on Medical Equipment, Orthopedic Rehab, Clinical Chemistry, Dental, Pharmacy and Hospital Services.

Available Market Research

Industry highlights available at ***export.gov/brazil***.

Bulgaria

Summary

The Government of Bulgaria is implementing a fundamental reform of its healthcare sector.

The health sector reform project has several components, the first one being reform and sustainability of the primary and ambulatory care sector. It provides practice equipment for primary health care and training in general practitioner (GP) practice management. The project also funds physician's offices' information systems, an information campaign and a labor adjustment strategy, as well as a health reform investment program to provide low-interest loans to physicians.

The second component targets reform of the hospital system, including introduction of Clinical Paths, similar to Disease Related Groups (DRG), assigning critical-diseases' tenders to be run by hospitals instead of Ministry of Healthcare; funding hospital information systems, financing a health reform investment program, reduction in number of hospitals; optimizing their functionality and funding a labor adjustment strategy.

The third component aims at assisting the National Health Insurance Fund (NHIF) in establishing the technological infrastructure for efficient functioning of the insurance system, including necessary hardware and software systems, as well as training and technical assistance required. The fourth component is aiming at strengthening the management and institutional capacity of the Ministry of Health, the NHIF, and the health system in general.

Another aspect of the healthcare reform relates to measures taken for the eradication of pandemic diseases. As an entry point to EU veterinary markets, Bulgaria is required to undertake strict sanitation and eradication measures relating to veterinary pandemic diseases such as Classic Swine Fever, Foot-and-Mouth disease, and Bird Flu. The Bulgaria Ministry of Agriculture and Food is responsible for these efforts.

Bulgaria's healthcare budget for 2009 and 2010 amounted to 1.573 billion EUR and 1.329 billion EUR respectively. The healthcare budget for 2011 amounted to 1.659 billion EUR (4.2% of GDP) and for 2012 it is estimated at approximately 1.875 billion EUR. For the long-term period 2001 through 2012 the healthcare budget ranged between 3.8 to 4.4% of GDP. The current health sector strategy urges increasing the demand for all subsectors' modernization and upgrades, which in general translates into:

Statistics

Capital:	Sofia
Population:	7,476,000
GDP:	USD 53.51 billion
Currency:	Bulgarian Lev
Language:	Bulgarian

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- Demand for invasive and noninvasive surgery equipment, oncology, ultrasound equipment, in-vitro diagnostic equipment, urology equipment, laboratory and testing equipment, diagnostic imaging equipment, equipment for haemodialysis, tissue and blood bank related equipment, veterinary turnkey project equipment, hospital care equipment, information systems, modern patient monitoring systems, hospital management systems, new high tech products such as laser instruments, MRI and computerized systems for cosmetic, dental, aesthetic and restorative medicine.
- X-ray systems, dental mechanical tools and instruments, dental surgery services, surgical tools, chairs, ultrasound equipment, photopolymer equipment, physiotherapy equipment, abrasive tools, maxillary surgery, anesthetics, sterilizing equipment, fittings, appliances, metal workplaces, ceramic work places and plastic workplaces
- Telemedicine and the introduction of an electronic healthcare portal to be based on unified healthcare database files for every Bulgarian citizen fully compatible with EU standards.

Market Entry

There are no specific challenges to the business environment which could be considered a serious threat. The institutions responsible for regulatory monitoring of market entry rules and laws are the Ministry of Healthcare (***www.mh.government.bg***), Bulgarian Drug Agency (***bda.bg***), National Health Insurance Fund (***nhif.bg***), National Veterinary Institute (***vetinst.bg***)

Current Market Trends

Among the healthcare short term priorities outlined by current and former Ministers are the improvement of prophylaxis and prevention in the fields of maternal healthcare, improvement of emergency care, improvement of junior dental healthcare, early diagnostics of breast and prostate cancer; introduction of new non-invasive surgeries, reduction of prices for drugs; introduction of high-tech biotechnology and products.

Another aspect of healthcare reform is related to the measures which have to be introduced by the Bulgarian Ministry of Agriculture and its newly established Food Safety Agency concerning sanitation and eradication of pandemic diseases. Being the entry point to the EU veterinary markets, Bulgaria is mandated to carefully and strictly undertake sanitation and eradication measures of any possible veterinary pandemic diseases such as Classic Swine Fever, Foot-and-Mouth disease, Bird Flu.

Main Competitors

Main competitors are all major EU companies which have maintained a presence in the local market for decades. Some Asian firms are also present in the local healthcare market.

Current Demand

Best sales prospects are generally outlined in the previous sections of the present report.

Registration Process

Mandatory required certifications are the CE mark as well as some ISO standards such as ISO 9001, ISO 13485, ISO 13795.

Medical equipment and consumables, which are subject to the mandatory registration regime can be viewed on the web page of the Bulgarian Drug Agency (***bda.bg***).

Few exceptions are made in cases where Bulgaria has Mutual Recognition Agreements with individual US companies, which have production facilities outside of the USA.

Barriers

There are no significant barriers on healthcare products in Bulgaria.

Some tariff and non-tariff barriers are reported in the pharmaceutical market sub-segment which are reported by the LAWG in Bulgaria and are included in the National Trade Estimate report.

Trade Events

Medicus, Dento, Galenia

October 30–November 2, 2013 • Plovdiv, Bulgaria
Pharmaceuticals, laboratory equipment, and dental technology.

BaSS (Balkan Dental Society)

Meets annually • Varna, Bulgaria

American Healthcare & Natural Products Expo 2013

February 29–March 1, 2013
US healthcare technologies, products, and equipment

Available Market Research

- Bulgaria Dental Equipment Market Overview
- Bulgaria Pharmaceutical Market Overview

Chile

Summary

As the United States-Chile Free Trade Agreement (FTA) concludes its eighth year, trade in products and services continue to be a resounding success. As of January 1, 2004, duties were reduced to zero on 90% of U.S. exports to Chile with all remaining tariffs to be phased out by 2015. In 2011, bilateral trade between the United States and Chile reached US$ 24.8 billion, an over 300% increase over bilateral trade levels before the U.S.-Chile FTA was implemented. U.S. exports to Chile in 2011 reached a record US$ 15.8 billion while imports from Chile reached US$ 9 billion. In 2010, the United States and Chile concluded the negotiations of a bilateral tax treaty that has not yet been ratified in either Congress. The United States remains the single largest cumulative direct investor in Chile, representing 24% of all net foreign direct investment from 1974 to 2011. Spain follows closely with 20.8%, and Canada is third at 18.5%. However, Canada has led all nations in investment from 2009 to 2011. Macroeconomic stability and growing integration with international capital markets has earned Chile an A+ credit rating, the highest in Latin America.

Chile remains one of the most stable and prosperous developing nations and consistently ranks high on international indices relating to economic freedom, transparency, and competitiveness. It also fares very well in terms of democratic development, gross domestic product per capita, freedom of the press.

Chile spends approximately 7% of its GDP in healthcare. The 2012 public healthcare budget considers strengthening primary healthcare attention, and the construction of 24 new outpatient centers. This focus is based on the epidemiologic reality of the Chilean population: there has been an increase in chronic diseases, the population is aging, and many primary healthcare conditions go unsolved. To achieve this goal, the plan considers an increment in the number of healthcare professionals, the reconstruction of 7 hospitals, and investment in information technology for interconnected digital medical records.

The public healthcare system is comprised of 183 hospitals: 59 high-complexity, 24 medium-complexity and 100 low-complexity hospitals. In all, the public sector has approximately 26,300 beds. In the private sector, there are 109 hospitals, with approximately 15,000 beds. There are a considerable number of expansion projects currently ongoing in the private sector, and also new investments in the sector are considered nationwide. FONASA, the government-run healthcare insurance system, covers 75% of the population; of the remaining 25%, approximately 5% lacks any type of insurance, and 20% (bordering on 2.6 million people) pay into the private sector insurance system provided by 7 entities called ISAPRES. Since 2005, Chile has a healthcare

Statistics

Capital:	Santiago
Population:	17 million
GDP:	USD 248.9 billion
Currency:	Peso
Language:	Spanish

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program, consisting of government-funded subsidized healthcare coverage for currently 69 diseases considered to be high-incidence. Information on the pathologies covered by this program may be found at ***www.fonasa.cl/wps/wcm/connect/Internet/SA-General/Asegurados/Plazos+del+Auge***

Market Entry

U.S. medical equipment and devices are well regarded in Chile. A strategy that has proved successful for U. S. companies interested in the Chilean market is to appoint a qualified agent or distributor. Chilean distributors in the medical sector are usually knowledgeable, experienced, and with a good network of sales people throughout the country. Reliable after sales support is a priority in this market.

The metric system of weights and measures is standard in Chile. The electric power supply is 220V 50Hz. Since the implementation of the U.S.-Chile Free Trade Agreement, in 2004, medical equipment, medical devices, and pharmaceuticals enter Chile duty-free, provided a U.S. certificate of origin is presented to Chilean Customs. Imports to Chile, alike all foreign and domestic products are subject to Chile's 19% VAT (Value Added Tax).

Mandatory registration at the Institute of Public Health is required for all pharmaceuticals. Medical devices such as preservatives, gloves, needles, and syringes have to be quality tested. The Ministry of Health is currently discussing imposing special requirements for medical implants in the near future.

Current Market Trends

U.S. state-of-the-art medical technology has good market potential in Chile, especially in the private sector that has considerable expansion projects. The Chilean private healthcare system is well regarded in the region. Private hospitals receive foreign patients for treatment on a regular basis, Some of these private hospitals have Joint Commission accreditation; therefore maintaining high standards is a permanent goal. Many Chilean physicians have U.S. post-graduate degrees and maintain regular contact with important U.S. healthcare institutions.

Main Competitors

The majority of the medical equipment present in the Chilean market is imported. Local statistical data shows that the United States has approximately 40% of Chile's market share, followed by Germany with some 15%, and Japan with approximately 7% market share. Price is an extremely important factor, especially in the public sector where limited funds cover a large segment of the population. The private sector is also price sensitive, but is far more likely to consider recognized brands that have good quality and after-sales reputation.

Current Demand

The following list of equipment is currently on demand in Chile:

- Autoclaves
- Surgical tables
- Non-disposable and disposable surgical instruments
- Cardiology equipment including pacemakers
- ECG monitors (low and medium complexity)
- Ventilators
- Infusion pumps
- Aspiration pumps
- Central monitors
- Echo tomography equipment
- Mobile incubators
- Trauma equipment
- Anesthesia instruments and appliances
- Ophthalmoscopes
- Hospital beds

Barriers

Chile has a favorable import climate. There are no known barriers to U.S. medical equipment, devices, pharmaceuticals, laboratory equipment, or diagnostic test.

Trade Events

Expo Hospital

July 24–26, 2013 • Espacio Riesco, Santiago, Chile • ***fisa.cl***

International trade fair for equipment, devices, technology, and services used in the healthcare industry.

Available Market Research

- Medical Equipment Industry Overview, 2011
- Nutritional Supplements Industry Market Insight, 2010
- Cosmetics Industry Overview, 2010
- Pharmaceutical Industry Overview, 2009

People's Republic of China

Summary

China is now the world's 2nd largest market for medical equipment. It offers significant potential for U.S. companies interested in expanding into the Chinese market with the huge demand for better healthcare services driven by increasing aging population and improved medical insurance coverage. While the Chinese medical device companies provide low to mid-range technology and products, they generally lack the expertise and experience deemed appropriate by Western standards. The Chinese also view foreign medical device companies as more credible than their Chinese counterparts. The Chinese healthcare market is poised to be explored by those foreign enterprises interested.

Market Entry

According to statistics from World Trade Atlas (China Customs), by the end of 2011, China's import and export value reached US$21.6billion, an increase of 23% over 2010. Please see the top three countries in the import and export of medical equipment to China from 2010 to 2011. It shows that U.S. is the top exporter of medical devices to China, accounting for over 30% of the total followed by Germany and Japan:

Country/ Region	Medical Device Import Value (in USD billions)				Medical Device Export Value (in USD billions)			
	2010	Share %	2011	Share %	2010	Share %	2011	Share %
World	7.17	100	8.54	100	10.39	100	13.06	100
U.S.	1.79	32	2.06	30	3.59	33	4.43	32
Germany	0.5	8	0.62	7	1.8	18	2.34	19
Japan	2.83	8	0.96	8	1.68	14	2.07	14

Source: World Trade Atlas (China Customs). HS Code: 9018, 9019, 9020, 9021, 9022,382200,902780,902750,902730,902720

Current Market Trends

China is the most promising medical device market in the world. Its annual growth rate has been at 15% to 20% depending on products. Based on the BMI (Business Monitor International) report, China's medical equipment market reached a total size of RMB117 billion (US$18.2 billion) in 2011. Major

Statistics

Capital: Beijing
Population: 1.35 billion (est. 2011)
GDP: USD 7.212 billion
Currency: Renminbi (Rmb)
Language: Mandarin Chinese

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driving factors include demand for better healthcare services, the increasing aging population, and the improved and full medical coverage for all nationals

.Recently, the Ministry of Health (MOH) has issued the notice to promote the development of non-public medical institutions to meet the shortage of medical resources, requiring giving priority approval should be given to privately-invested medical institutions that meet entry standards when adjusting or increasing new healthcare resources. It stated that by 2015 the number of beds and services should account for about 20% of the total. This will lead to greater needs for medical equipment in the future.

Main Competitors

Depending on the specific type of products, foreign competitors are those from EU or Japan as their respective markets for healthcare are structured and well developed.

Current Demand

Chinese end users consider U.S. products to be of superior quality and most technologically advanced. China's hospitals particularly welcome medical equipment and products with high content of technology. At the same time, domestic medical device companies are consolidating, upgrading quality, and beginning to compete in medium-level technology niches.

Registration Process

All imported medical devices are required to register with the State Food and Drug Administration (SFDA) before being sold in the Chinese market. The SFDA has a comprehensive system for medical device registration and inspection, which includes product type testing and factory audits. Medical devices are divided into three classes depending on levels of risks similar to but stricter than that of USFDA. Clinical trials are required for registration of Class III and some Class II medical devices. The process normally takes from one to three years.

Barriers

Barriers exist with an uncertain regulatory environment and extensive delays in registration and re-registration of products, although efforts are reportedly being made to reduce the large backlog. Additionally, pricing, tender, and bar code systems also play a role of delaying a company's entry into the Chinese medical device market.

Trade Events

China Med 2013

March 28–30 • Beijing • ***www.chinamed.net.cn/en***

One of the most influential exhibitions in Chinese medical instruments and equipment industry.

China International Medicinal Equipment Fair (CMEF) 2012 Autumn

October 18–21 • Chengdu, Sichuan

China International Medicinal Equipment Fair (CMEF) 2013 Spring

Date TBD • Shenzhen • ***cmef.com.cn/en***

Founded in 1979, CMEF is held twice a year in Spring and Autumn. CMEF has become the largest exhibition of medical equipment and related products and services in the Asia-Pacific region.

MEDTEC China 2013

September • Shanghai • ***medtecchina.com/index.php?page=home-en***

Allows manufacturers access to the latest technologies, techniques, and equipment. Experts now attend MEDTEC China on an annual basis to view and learn, to meet suppliers, and to attend seminars.

Care & Rehabilitation Expo China 2013

November • Beijing • ***crexpo.com.cn/english***

China's largest exhibition focused exclusively on the care and rehabilitation industry.

SINO-Dental 2013

June 9–12 • Beijing • ***sinodent.com.cn/en***

China's largest dental exhibition, organized by the Ministry of Health. In 2011, 74241 professionals from 80 countries and regions were in attendance.

Available Market Research

- Clinical Laboratory Market: ***buyusainfo.net/docs/x_5325735.pdf***
- Ophthalmic Equipment and Products Market: ***bit.ly/NkQbIX***
- Gynecological Devices and Products: ***buyusainfo.net/docs/x_3244830.pdf***
- Pre-hospital Emergency Medical Service and Equipment: ***buyusainfo.net/docs/x_918621.pdf***
- Measures for the Administration of Medical Device Registration (English Translation): ***buyusainfo.net/docs/x_525872.pdf***

Czech Republic

Summary

The health care sector is very active and prominent in the Czech Republic. Czech healthcare system reform has been one of the most important political topics. Massive changes were prepared in two stages—from January 1st and then from April 1st 2013. The first stage includes changes in fees, above-standard services and a switch of insurance companies. The second stage brings three reform bills—on health services, specific and emergency health services, and an amendment to the Act on Public Health Insurance. The system is predominantly financed by the public sector through mandatory insurance. Approximately 76.6% of total health expenditures are covered by compulsory health insurance; the state and territorial budgets covered 7.2% and private voluntary expenditures covered 16.2%. The share of private expenditure in the total expenditure on health rose particularly after year 2008 due to new regulation fees in health services. Total expenditure on health amounts to nearly $14 billion ($1.330 per capita), which represents about 7.7% of the country's GDP. The market has proved generally resilient to the economic downturn. Although the government is examining ways to reduce healthcare expenses, including limiting purchases of expensive equipment and pharmaceuticals or adopting e-tenders, which would procure equipment via tenders based solely on the cost of the equipment, the Czech Republic offers strong opportunities for medical device companies. Expected growth in the sector over the next couple years is ca. 7%.

Market Entry

To import medical devices into the Czech Republic, a foreign producer should have an importer in the Czech Republic. To sell medical devices in the Czech market, several points are important:

1. Medical devices have to obtain the CE mark (if required),
2. Medical devices have to have directions for use enclosed in the Czech language,
3. The Declaration of Conformity has to be submitted (in the Czech language),
4. The Czech importer has a notification duty at Ministry of Health. Medical devices and pharmaceuticals are also subject to a customs duty and a value added tax (VAT).

Current Market Trends

One of the most basic issues facing healthcare in Czech Republic is the spiraling cost of healthcare. Current market trends reflect increasing life expectancy and unhealthy lifestyles (obesity and heart disease are on the rise). Devices used to

Statistics

Capital:	Prague
Population:	10.5 million
GDP:	USD 205.950 billion
Currency:	Czech Crown (CZK)
Language:	Czech

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monitor symptoms and manage disease are in increasing demand. The most common cause of death is circulatory system problems (heart disease, stroke etc.). Czechs continue to be heavy smokers, and the air in many industrial cities is somewhat polluted. Growing interest in joint Czech-U.S. projects in the health care field could generate new opportunities for U.S. medical equipment providers. The most significant project to date is the International Clinical Research Center (ICRC) at St. Anne's Hospital in Brno, which includes collaboration with the U.S. Mayo Clinic. Other Czech regions are eager to develop similar projects, and U.S. partners are in demand.

Main Competitors

The Czech Republic has a small but skilled medical device manufacturing sector. Production is at the low to medium end of the technology scale, but is increasingly of good quality. Local producers focus on exports, an estimated three-fourths of production is exported. Around 80% of the medical device market is supplied by imports mainly from the U.S. and other European countries. Germany and U.S. were the leading suppliers, accounting for almost 50% of all imports. Also other countries like Netherlands and Belgium play an important role in the domestic imports.

Current Demand

In the Czech Republic the best market opportunities exist for cutting-edge, high-quality sophisticated medical equipment, especially equipment that increases efficiency and reduces occupancy rates in hospitals. Best prospects include mini invasive surgery systems (MIS), patient monitoring systems, video endoscopes, digital image processing, high-end ultrasounds, and home-care equipment.

Barriers

One of the challenges manufacturers and importers of medical devices and pharmaceuticals will face is getting the product on the reimbursement scheme that is covered by the insurance companies. This can, in some cases, be a time consuming process. Also, products from non-EU countries are subject to import duties. Customs duty rates are updated annually and are harmonized within EU countries. The import duty for medical device depends on the specific product and matching HS code. In general, duties range on average from 0–5 %. Electrical installations in the Czech Republic operate on 50 hertz cycles; power is supplied at the rate of 220V (single phase), and 220V and 380V (triple phase).More than half of Czech company representatives are able to communicate in English or in German.

Trade Events

PRAGOMEDICA + NON-HANDICAP

April • Prague • ***incheba.cz/en/veletrh/pragomedica.html***
One of the two largest medical fairs in the country, combined with a specialized fair for the handicapped.

PRAGODENT

October • Prague • ***pragodent.eu/en.html***
Focused on dental care, services and hygiene.

MEDICAL FAIR + REHAPROTEX

October • Brno ***bvv.cz/en/medical-fair-brno*** • ***bvv.cz/en/rehaprotex***
Focused on prosthetics and orthopedics, pro senior, health/wellness, and e-health segments.

OPTA

February • Brno • ***bvv.cz/en/opta***
One of the most important Central and Eastern European fairs for eye optics and ophthalmology.

EXPODENT

October • Prague • ***bvv.cz/en/expodent***

Dental medicine and oral hygiene.

Available Market Research

- Healthcare IT (2010)
- Eye Care Market (2009)
- Dental Market (2009)
- Medical Device Market (2008)

Denmark

Summary

Healthcare is an important part of the Danish welfare system. About 85 percent of total healthcare costs are financed through taxes. A fundamental principle is that all citizens have the right to good health and healthcare on equal terms, regardless of income.

The healthcare sector has three political and administrative levels: the government, the regions and the municipalities (national, regional and local authorities). Denmark is divided into five regions and 98 municipalities that cover at least 20,000 inhabitants each. The regions are responsible for providing hospital care and they own and run hospitals and prenatal care centers. They allocate finances for GPs, specialists, physiotherapists, dentists and pharmacies. The municipalities are mainly concerned with preventive care and rehabilitation.

Nearly 5 million Danes, or 90 percent of the population, contact their doctors annually, and approximately 1 million are admitted to the hospital annually. About 1 million people visit the emergency room and 6 million outpatient procedures are conducted. While the number of hospitals in Denmark has decreased in the past decade, the number of hospital visits has increased, bringing facilities near capacity and providing incentives for more efficient methods of treatment.

There are 90 hospital-premises and in 2010 there were 14,335 full time doctors working in public hospitals, 34,330 full time nurses in public hospitals, and 24,348 other full time employed personnel (Ministry of Interior and Health, 2011). Over the next couple of years, about 7 billion USD will be invested in 16 new (or renovated) modern hospitals.

Market Entry

The Economist Intelligence Unit ranks projects that Denmark will continue to be the best business friendly environment until 2013. This finding was based on Denmark's pro-business policies, structural reforms to enhance labor market stability, and a fiscal policy that preserves the large amount of public services while achieving budget surpluses. Its flexible labor market and highly educated workforce are particularly attractive to businesses.

Recommended entry modes vary with the different subsectors and nature of the product. Sale of medical devices is typically seen with a traditional distribution model, whereas pharmaceuticals and health IT products may require local presence or a strategic partnership with a local vendor. For the biotech sector, strategic proximity to the local big pharma sector may also be

Statistics

Capital:	Copenhagen
Population:	5.5 million
GDP:	USD 320 billion (2011)
Currency:	Danish Crown
Language:	Danish

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the best solution, possibly by being co-located with a university or other research institution. Contact local trade specialist for further guidance.

Current Market Trends

Total healthcare expenditure in Denmark has expanded faster than GDP over the past decade and now accounts for 11 percent of GDP. This increased spending on healthcare in Denmark will continue to increase in the upcoming years due to the country's ageing population since around one-third of hospital expenditure goes to those over 66 years of age. In 2009, the estimated public health care spending was around USD 33 billion. This figure is expected to be in the USD 35 billion range in 2014.

Main Competitors

Denmark has many local manufacturers that posses fair shares in the global market. They specialize in the production of hearing aids, diagnostics, orthopedic and prosthetic devices. Denmark is home to major companies in both the medical device industry and the biotech and pharmaceutical industries, including Novo Nordisk, Lundbeck, Bavarian Nordic, Coloplast, GN ReSound, Oticon and Widex. About 90 percent of the local production is exported.

Current Demand

The average life-expectancy is 76.3 years for men and 81.1 years for women, which is amongst the lowest in Europe. The low life expectancy may be explained by the fact that Denmark's medicine expenses per capita is amongst the lowest in Europe.

The most common causes of death are various forms of cancer (28 percent) and cardiovascular diseases (28 percent). Chronic obstructive pulmonary disease, neuropsychiatric conditions (Alzheimer, alcohol abuse, and Parkinson), diabetes, and digestive diseases (peptic ulcer disease and cirrhosis of the liver) are also common causes of death.

It should be noted that since healthcare in Denmark is free, Danes are very reluctant to spend money on healthcare and treatment themselves. Nevertheless, 89 percent of the Danish population was very or somewhat satisfied with using public services, i.e. consulting a GP, in 2011 (Statens Institut for Folkesundhed, 2011), and Danes are also generally concerned about their health and are willing to spend money on preventive measures including healthy food, dietary supplements and gym memberships.

Barriers

All products sold in Denmark must carry the CE mark. Various agencies under the Ministry of Interior and Health govern any additional certification and registration procedures in addition to standard EU requirements. Labelling and instructions manuals must be available in Danish (e.g. inserted).

Trade Events

Lægedage
laegedage.dk

Health & Rehab Scandinavia
health-rehab-scandinavia.com

Scandefa
scandefa.dk

eHealth Observator
e-sundhedsobservatoriet.dk

Available Market Research

Medical technology; dental equipment; lab equipment; biotechnology with healthcare application; pharmaceuticals; vitamins and food supplements; healthcare services; telemedicine; health IT.

Dominican Republic

Summary

In the Dominican Republic, the demand for medical equipment and supplies will continue to grow over the next years driven by the changes in the Dominican Social Security law, the steady growth in the number of privately-owned hospitals, and the continually-rising need for medical products for a growing population. There is a strong preference for U.S. goods, provided the prices are competitive. U.S. exporters of medical equipment and supplies to the Dominican Republic enjoy numerous advantages, including the positive reputation as manufacturers of good quality; quick delivery time; close proximity to the U.S. that results in reduced shipping charges; and small order accommodations. Since many Dominican physicians have been trained in the U.S., they are highly receptive to U.S. products.

Market Entry

U.S. products and services enjoy favorable access to the Dominican market. The Central American Free Trade Agreement-Dominican Republic (CAFTA-DR) provides for duty-free entry of medical equipment and pharmaceutical products. To succeed in the Dominican market in the healthcare sector, it is advisable to have a local distributor that can provide after-sales and leasing services, support guarantees, and maintain inventories for parts and supplies. Exporting directly to the private hospitals can be extremely challenging since procurement practices in public hospitals dictate that all purchases must be made through a local Dominican company. Local importers and distributors usually have sales agents who distribute the products to small retailers throughout the country. Local distributors also conduct promotional activities to encourage doctors and nurses to use and recommend their products. However, U.S. exporters should seek local legal counsel prior to signing a representative agreement with a Dominican agent to ensure that their rights to terminate an agreement in the future are safeguarded.

Current Market Trends

The Dominican market for medical equipment and supplies depends on imports. This market, which is largely dominated by U.S. exporters, has maintained a consistent demand for equipment. It is expected to continue growing, due to a very competitive situation between private- and public-sector healthcare facilities for the acquisition of modern technologies in machinery and equipments. Price is the primary determining factor for the purchase of disposable such as gauze, surgical drapes, surgical catgut, and the like. However, when purchasing surgical sterilizers, ophthalmic surgery instruments, breathing appliances and gas mask, etc., quality is the deciding criterion. The

Statistics

Capital:	Santo Domingo
Population:	10 million
GDP:	USD 94.58 billion (est. 2011)
Currency:	Dominican Peso
Language:	Spanish

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public sector bases most purchasing decisions largely on price and is very often more receptive to less expensive products even if the quality might be questionable.

Main Competitors

U.S, companies have 65 percent of the Dominican import market for medical equipment and supplies. There is extensive local production of surgical instruments and supplies. However, 95 percent of this production is exported through the Free Trade Zone (FTZ) Program. Products manufactured in these FTZs include; wound management products (wadding, gauze, and bandages), general surgery and minimally invasive surgery Instruments, ophthalmic surgery instruments, disposables (syringes, needles, catheters, surgical gloves, clothing for operating rooms, and surgery sponges). There is limited manufacture of surgical supplies beyond the FTZs and this production is not sophisticated, mainly involving textile products (gauzes, bandages, and surgical drapes).

Current Demand

Best Prospects:

1. **Surgical Instruments and Disposable Supplies:** Public hospitals and private clinics are by far the largest potential users of surgical instruments and supplies. For disposable surgical products such as gauze, adhesive dressings, sterile surgical catgut, sterile suture materials and sterile tissue adhesives for surgical wound closure, the primary purchaser and user is the Dominican government. For more technologically advanced surgical products, such as sterilizers, the most important purchasers are the private clinics.
2. **Homecare Medical:** The incidence of respiratory difficulties and diabetes, the aging of the Dominican population, and the CAFTA-DR free trade agreement are the primary factors behind the industry's 10 percent growth over the next three years. The market for these products is almost entirely supplied by imports and U.S. products enjoy a positive receptivity (65 percent of the market).
3. **Used/Refurbished Medical Equipment:** The Dominican market offers opportunities to exporters of used and refurbished medical equipment, especially that which has been refurbished by the manufacturer, who can use original replacement parts and provide a limited guarantee. In addition, buyers of used equipment usually require assurances that parts and maintenance can be obtained locally. Therefore, U.S. firms interested in this market should appoint a local distributor. The market for used devices (not refurbished) is limited to hospital furniture such as operating tables and hospital beds. There are good opportunities for these products, which do not always need to be refurbished and will generally be accepted with minor defects such as scratches and tears. The Dominican government does not impose restrictions on the importation of used/refurbished medical equipment. All imports of both new and used equipment are treated equally.
4. **Diagnostic Equipment:** Tomography equipment represents a very large percentage (approximately 69.1%) of the imports for diagnosis and imagery medical equipment, along with the corresponding supplies and spare parts.

Barriers

There are no significant trade barriers. Registration of healthcare products is required for drugs and medical devices only. The Dominican government institution responsible for issuing the Sanitary Registration certificates is the Department of Drugs and Pharmacies (Departamento de Drogas y Farmacias). For more information on the Sanitary Registrations, please visit ***drogasyfarmacias.gov.do***.

Available Market Research

- Regulations on Registration of Pharmaceutical Products
- Dominican Market for Used/Refurbished Medical Equipment

Egypt

Summary

The healthcare sector in Egypt, although large compared to its Middle East counterpart, has been relatively stagnant over the past few years. That being said, there should be a variety of investment opportunities as the Egyptian government is very keen on expanding the healthcare industry, especially relating to medical devices. In 2011, healthcare was responsible for 6.3% of GDP and total spending is expected to amount to $16.6 billion in 2012. Consumer healthcare grew by 12.6% in 2011 and spending is expected to reach $7.1 billion in 2012. The World Bank estimates that the average life expectancy for Egyptians has increased from 69 to 73 from the years 2000 to 2009. While the government has done much to mitigate disease in the country by way of supplying cleaner water and increasing immunization rates, hepatitis C still remains rampant as 9.8% of the population is believed to be infected with it and it seems to grow at a fixed rate of 500,000 new cases a year. The Ministry of Health operates 1300 hospitals which correspond to a supply of 60% of beds. Universities, the Army and the private sector constitute the other 40%. Healthcare expenditures by the government totaled $4 billion which is a 17% year-on-year increase.

Market Entry

U.S. medical equipment and products are traditionally well-received in Egypt due to their perceived high quality. Egyptian law requires that for public tenders, foreign companies must retain Egyptian commercial agents. However, most U.S. companies have found it beneficial to engage a local agent to handle the problems associated with communications, bureaucratic procedures, local business practices, and marketing.

Based on geographical location or product basis, a firm can appoint multiple agents in Egypt to further enhance its success. Agent commissions would vary with services provided and the amount of individual contracts.

Supplying reliable after sales service as well as spare parts and maintenance services is a key to maintaining a competitive advantage. Agents of medical equipment have found that keeping approximately 40% inventories of spare parts will satisfy the needs and demands of their clients. FDA approval is a key to having medical products registered and approved by the MOH in Egypt, although the MOH may still do additional testing on any medical device. The importation of used and refurbished medical equipment and supplies into Egypt is banned without prior approval of the MOH.

Statistics

Capital:	Cairo
Population:	82 million
Currency:	Egyptian Pound
Language:	Arabic

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Current Market Trends

Egypt's medical device market is the second largest in the Middle East, but one can attribute that to the sheer number of people residing in Egypt. More specifically, Egyptians only receive 2.5 medical tests per year as opposed to Saudi Arabia where they undergo 6 medical tests per year. Medical devices contributed $538 million dollars to GDP in 2011, which was a mere .22% of total GDP and 5.1% of total healthcare spending. Total sales in medical devices totaled at $.54 billion, which was a 4.76% increase from the previous year. Since 2008, sales in medical devices have increased by 25.5% or at a compound average of 6.39% per year since 2008. The strong growth despite the economic downturn is a strong indicator of increased demand. Furthermore, 32% of the Egyptian population is under 14 which indicate a strong need for investment in the healthcare industry. Furthermore, recent reports have indicated that the Egyptian government prefers investments in preventative medicine which is a specialty catered to medical devices. According to the World Bank, under less than 5% of total investments are allocated toward health services. With the strong demand and less barriers to market, the medical device sector will be ripe for a substantial economic growth in the midterm.

Main Competitors

Main competitors are from Germany, China, and India.

Current Demand

Opportunities for U.S. exports to Egypt's medical equipment and services market are substantial and cut across the entire spectrum of medical-related activities and needs.

U.S. suppliers are strongly encouraged to pursue opportunities in the following subsectors:

- Oncology and high-tech radiological equipment
- Highly specialized disposables
- High-tech surgical and medical equipment
- Software for hospital management/network
- ICU monitoring equipment
- Sophisticated laboratory and scientific equipment
- Mobile clinics

Registration Process

The Drug Policy & Planning Center (DPPC) of the MOH requires the following documents in order to register and approve medical devices and equipment:

- Original Free Sale Certificate (issued by official health authorities in the country of origin, stating that the product is freely sold), certified by both the Chamber of Commerce and Egyptian Embassy/Consulate.
- Copy of Pro-forma Invoice.
- Copy of FDA approval (Certificate to Foreign Government) certified by the Egyptian Embassy/Consulate (importer may be required to show the "original" certificate for confirmation.)
- Copy of the legalized Agency Agreement.
- Certificate of Origin (if case of exporting components to a factory for local manufacture/assembly).
- Declaration of Conformity (in case of class 1 non-sterile devices, non measuring product or equipment).

Barriers

- **Red Tape:** Although the economic reformers have developed considerable momentum, red tape remains a business impediment in Egypt.
- **Non-Transparency:** Working directly with the government is time consuming and bureaucratic, and the tender announcement process is not fully transparent. Identifying a good, well-established local agent is key to navigating the system.

European Union

Summary

As the European Union (EU) does not have a Food and Drugs Administration (FDA), the task of harmonizing requirements and regulating medical devices is handled by the European Commission in close cooperation with Member State's Health Authorities. The purpose of the EU harmonization effort is to merge the differing national requirements into one law which can be applied throughout the European Union. Legislation adopted through this process covers implantable, non-implantable and in vitro diagnostics medical devices in three separate directives that provide manufacturers the basics to certify their compliance with EU-wide safety requirements.

Adopted Legislation

The following EU directives are in force throughout the European Union consisting of 27 Member States (Austria, Belgium, Czech Republic, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxemburg, Malta, the Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Romania, Bulgaria and the United Kingdom):

- **Active implantable medical devices (90/385/EEC):** Active implantable medical devices (AIMD), such as heart pacemakers or defibrillators are defined as "any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure." Considering the potentially high risk factor of such devices for the patient, manufacturers cannot self-certify and have to rely on the services of an accredited test laboratory to complete the process of compliance.
- **Medical devices (93/42/EEC):** Medical devices are broadly defined as "any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings" for several purposes such as diagnosis, treatment, alleviation of disease and more. As the range of this directive is broad and leaves room for interpretation, the Commission has written guidance for manufacturers. Medical devices include syringes, bandages, wheelchairs, endoscopes, prescription glasses and contact lens solution among others. As the range of devices covers minimal risk as well as higher risk devices, the classification of the product will determine whether a manufacturer can self-certify or needs to involve the services of an accredited test laboratory.
- **In vitro medical devices (98/79/EC):** An in vitro diagnostic device (IVD) is a "reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system whether used alone or in combination intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the

Statistics

Capital:	Brussels, Belgium
Population:	501,259,840
GDP:	USD 14.793 trillion
Currency:	Euro (€)

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human body solely or principally for the purpose of providing information." It covers items such as pregnancy test kits and blood analysis machines. While manufacturers of simple IVD test kits such as for diabetes can self-certify compliance with the requirements, more high risk test kits such as HIV will require the services of a notified body.

The directives have been supplemented over time by six modifying and implementing directives, including the last technical revision brought about by Directive 2007/47/EC which entered into force on March 21st, 2010. The main changes introduced by this directive impact medical devices and active implantable medical devices.

- The conformity assessment procedures and classification of devices as well as the essential requirements for active implantable medical devices (AIMDs) and medical devices (MDs) have been somewhat simplified, harmonized and enhanced.
- Software with an intended medical purpose is now a medical device in its own right.
- All certificates issued by notified bodies are limited to a maximum validity of 5 years.
- With the emphasis on clinical data for all devices in the new directive, the European Commission published guidance on the clinical evaluation dossier in December 2009.
- Use of PVC softeners in certain types of devices will require labeling. Following a mandate from the European Commission for medical devices, CEN, the European standards organization, has developed a standard EN 15986 which includes a symbol to show the presence of phthalates in medical devices.
- Custom-made devices will be subject to a post-market review system.

Since directive 2007/47/EC is not easy to read, the changes have been merged with the original directives to create a single, readable text which is up-to-date. The consolidated versions, as well as guidance, can be downloaded at:

- ***emergogroup.com/files/EUROPE-CONSOLIDATED-90-385-EEC.pdf***
- ***emergogroup.com/files/EUROPE-CONSOLIDATED-MDD-93-42-EEC.pdf***
- ***eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1998L0079:20090807:en:PDF***
- ***emergogroup.com/files/2007-47-EC-guidance.pdf***

CE Marking

Known as "new approach" directives, these directives outline a set of "essential requirements," rely on use of voluntary EU wide harmonized standards, and offer a choice of conformity assessment modules. The distinguishing feature of new approach directives is CE marking, which is a conformity mark, affixed to the product, the instructions for use and the packaging, an indication to inspection authorities that the product complies with the directives. The steps for compliance with EU medical device legislation are described below.

Exception to CE Marking

While CE marking is generally required on all medical devices, there are a few exceptions. All custom made implantable and non-implantable devices and devices for clinical investigations are subject to a different conformity assessment module which does not require CE marking at the end of the process. In vitro diagnostics for performance evaluation or research purposes only are not subject to the IVD directive, although they may be subject to national requirements. In general, devices shown at trade fairs, exhibits, for demonstrations etc do not need to have CE marking. However, it is recommended to indicate clearly that non-CE marked devices are for demonstration purposes only.

Classification

Manufacturers should note that the differences in regulatory approach between the EU and the U.S. mean differences in classification and compliance verification. It would be wrong to assume that meeting the requirements for the U.S. market would satisfy the EU requirements. To illustrate this point, hospital beds including accessories, according to FDA guidance, are either Class I or II depending on the type of bed. In the EU, hospital beds and accessories are classified as Class I devices, allowing self-certification. In addition, the beds and their accessories would have to be considered separately, each as medical devices in their own right, especially when such items are sold separately.

The AIMD directive has one class and does not allow self-certification. The medical device directive covers four classes, ranging from Class I, II a and b, to Class III. Only Class I devices can be self-certified. Manufacturers have to involve the services of a notified body in all other cases, and sterile Class I devices or those with a measuring function must also use a notified body. The IVD does not distinguish classes, but rather groups: general tests, self-testing kits, and Annex II lists A and B. For simple tests, self certification is usually an option. To help with classification in case the annexes in EU directives are difficult to interpret, the Commission has published new guidance at ***http://bit.ly/PfkVYa***.

Borderline Products

For the majority of medical devices, the purpose is obvious: pacemakers, endoscopes, syringes and wound dressing are clearly to be used for medical purposes. Products where the intended purpose is not so clear are known as borderline products and they may be subject to several directives. For example, a scale to weigh patients in a hospital would be subject to both the non-automatic weighing scale and the medical device directives. Disinfectants for exclusive use with a medical device may be classified as an accessory to a medical device because the intended purpose is medical rather than general. The intended purpose is usually supported by appropriate statements on the company's website or in promotional literature. It is possible to get an official interpretation to clarify borderline products but manufacturers should be able to make the determination in most cases themselves by using the guidance provided by the Commission.

The Commission released new guidance on borderline products in March 2011: ***bit.ly/QExPo6***.

Compliance with "Essential Requirements"

The "essential requirements" for the protection of health, safety and environmental concerns form the core of the directives. They cover risks and hazards that may occur at the design, production and handling stages. The manufacturer has to address the essential requirements which apply to a product and identify relevant risks for the patient. Non-relevant essential requirements do not have to be considered. As an example, manufacturers of arm braces made of stretch fabric would have to consider the essential requirements related to "compatibility between the materials used and biological tissues," in other words, the fabric's potential to cause skin allergies. A non-relevant requirement for arm braces would be "protection against radiation." Choice of packaging is an essential requirement for prepackaged devices, as damage resulting from mishandling could have an adverse impact on the device making it harmful for the patient upon use. These are just examples, bearing in mind that there are many other elements to verify and that the manufacturer should carefully review the complete list of essential requirements.

Use of EU-Wide Harmonized Standards

The task of complying with essential requirements can be simplified by voluntarily using EU (EN) harmonized standards. The risk assessment management standard which facilitates the initial checking of the relevant essential requirements is ISO/EN 14971. Manufacturers may also establish their own checklists for risk assessment of medical devices.

Other than the risk assessment standard mentioned above, the Commission has listed over hundred EU wide harmonized medical device standards addressing various essential requirements. These standards have been developed and/or identified by the European standards organizations. They are often based on international standards. References to EN standards are published in the Official Journal (the EU equivalent of the U.S. Federal Register). As a result, the standards are uniquely linked to EU legislation and are known as harmonized standards. Use of EU harmonized standards gives "presumption of conformity." When a manufacturer opts not to use an EU harmonized standard or prefers to design/manufacture to other standards, then the manufacturer has to show in great detail how their medical device meets the essential requirements in EU medical device legislation. All other existing standards not published in the Official Journal are either national or industry standards.

Modules of Conformity Assessment

To facilitate acceptance of the final product as meeting the requirements of the EU directive, the manufacturer will have to choose a conformity assessment module as described in the annexes of EU medical device legislation. The choice of the module is determined by the classification and the preference of the manufacturer for a given module. As there may be several options, the Commission created flow charts to facilitate the task of selection. The flow charts can be found in Annex 8 of the Guide to New and Global Approach, available online at ***bit.ly/QEzLwM***.

The conformity assessment modules address the design and production stages. For design, the manufacturer must provide the evidence of how the device meets the essential requirements. For production, the manufacturer has to put in place and document a quality system to ensure continuity in complying with the essential requirements.

Low risk products, such as Class I medical devices or self-test kits, generally allow self-certification based on conformity assessment module A which consists of establishing a Declaration of Conformity and compiling a technical file. All modules between B and H combine design and production compliance such as type examination and verification of manufacturing to type based on technical file inspection (modules B and F) or full quality assurance (module H). As these are conformity assessment modules for higher risk products, the services of an EU notified body or U.S. based subcontractor will be required to some degree depending on the classification.

Roles of a Notified Body

All active implantable medical devices and certain types of IVDs as well as medical devices belonging to Class II a or b or higher require the involvement of a notified body, the official term for accredited test laboratory based in the EU. Only notified bodies in the European Union can make the final assessment of conformity certification in accordance with EU directive(s). A U.S. based subcontractor of an EU notified body, such as UL or Intertek Testing Services, can also handle the tests for certification, but the certificate of conformity will still have to be supplied by the EU based notified body.

Technical File

The technical file contains all relevant information to support the claims of compliance with EU requirements such as a general description of the product, documentation of the quality system, design information, list of standards used, result of design calculations/inspections, test reports, performance evaluation data, sample of label and instructions for use, and Declaration of Conformity. It is to be kept either by the manufacturer or his/her authorized representative with the understanding that it should be quickly accessible upon request from an official national inspection authority.

Declaration of Conformity

Among the final steps in the CE marking process of medical devices is the drawing up of a Declaration of Conformity which consists of name and address of the manufacturer and/or authorized representative, product name, type, model number and any relevant supplementary information, the reference numbers of standards, the date, a signature with title and a statement regarding responsibility of manufacturer or authorized representative. By applying the CE marking on the product, packaging and on the instructions for use, which can be done either by the manufacturer or his importer/distributor, the manufacturer has completed the CE marking process.

Authorized Representative

Manufacturers outside the EU have to identify an EU-based authorized representative unless they have a registered business in the European Union. The primary task of the authorized representative is to be the point of contact for the national health authorities of the Member States. The representative will have to notify the national authority in the country of residence whenever a new Class I device is brought on the EU market. Some national authorities have standardized forms on their website. In addition, the authorized representative's name must be mentioned on the Declaration of Conformity.

The arrangement between the authorized representative and the manufacturer is purely administrative and subject to a commercial contract specifying the role that can be limited (authorized representative only) or broader (importer/distributor). Details about the responsibilities of manufacturers and authorized representatives can be found in the new legislative framework which covers all CE marking legislation.

Other than single notification, authorized representatives or manufacturers typically also register devices in individual member states. In the future, registration will become easier. With the Commission's 2010 Decision to enforce use of Eudamed—the EU-wide database for devices on the market registration of in vitro diagnostics in each country became redundant. The system for medical devices, however, will remain unchanged for the time being. Exporters/authorized representatives will still have to register their devices nationally until and when the Commission decides to move to a centralized registration for manufacturers of devices. In the meantime, Eudamed will be of use to member states for internal communications and for post-market surveillance purposes. To facilitate registration, the EU encourages use of the Global Medical Device Nomenclature (GMDN) based on EN/ISO standard 15225.

Post-Market Surveillance

As the EU regulator allows manufacturers to self declare conformity, with or without involvement of an accredited test laboratory, verification of compliance to ensure safety of consumers is left to the Member States after the products have been brought on the market. As Member States each have their own system, it is possible that some countries grant extensive inspection powers to their national customs service where others may focus their resources in local inspections. When caught in an infraction, the measures imposed on manufacturers may vary from a simple warning to a hefty fine or complete withdrawal from the market, depending on the type of infraction.

EU medical device legislation requires that Member States put in place safeguard procedures. In case of an incident involving injury or death, the Commission will be notified, thereby triggering an EU-wide rapid alert system as described in the EU's general product safety legislation. The Commission has been putting more emphasis on post-market surveillance, with a goal to strengthen the infrastructure of cooperation among national inspection authorities.

Coming Soon: New Regulatory Framework for Medical Devices

The existing medical device directives (MD and AIMD) are currently being reviewed following the 2008 public consultation. The purpose is to recast the regulatory framework. A proposal for a new framework is expected in 2012. The review focuses on extending the scope, possibly creating a Medical Device Committee within the European Medicines Agency (EMEA), improving the vigilance and post-market surveillance system, updating the regulatory framework after the revision of the New Approach and further aligning the EU system with the international regulatory principles of the Global Harmonization Task Force for medical devices (GHTF).

In June 2010, the Commission launched a separate public consultation to review in vitro diagnostic device legislation. The review focuses on scope, classification, and conformity assessment methods of IVDs.

For more information about the consultations, please visit ***bit.ly/RDKx6g***.

Medical Devices and Machines

Overlap with the new machinery safety directive 2006/42/EC has been clarified for medical devices that are also machinery. Only one single conformity assessment is required under the medical device directives 93/42/EEC and 90/385/EEC. The risk assessment to be carried out is the risk/benefit analysis as set out in the essential requirements of the directives concerning medical devices. Harmonized standards for medical devices which are also machinery should cover in their scope any requirements of the machinery directive that are applicable to the devices. Such standards will be reviewed and amended or revised if needed.

For more information, please visit ***bit.ly/Od4cUM***.

MRI Equipment

The European Commission is reviewing directive 2004/40/EC on electromagnetic fields. This directive impacts manufacturers of MRI (magnetic resonance imagining) equipment because it sets exposure limits for workers. Stakeholders affected by this directive lobbied the EU and Member States in order to obtain an exemption for MRI equipment. The European Commission published its proposal for a revised EMF Directive in June 2011. MRI equipment manufacturers were successful in obtaining an exemption for MRI from the binding exposure limits proposed in the Directive. However, the proposal will be scrutinized in the months to come by the EU legislator and may be modified.

Packaging/Labeling

The amended EU directive on units of measurement (the so-called "metrics" directive 80/181/EC) entered into force on January 1st, 2010, which means products must bear metric units of measurement. Use of supplementary units, such as U.S. customary inch-pound, are also allowed. Specific requirements for labels are included in medical device directives. As for choice of language on labels, EU medical device legislation defers to Members States. Please read our market research report on language requirements and/or contact our CS posts in other countries for more details.

Medical Devices Using Animal By-Products

The occurrence of bovine spongiform encephalopathy (BSE) in the European Union led to stringent measures regarding traceability of tissues of animal origin for use in medical devices. Risk assessment was addressed in guidance and standardization. The Commission adopted an animal by-product regulation in 2002, repealed in 2009 by Regulation 1069/2009, which covers use of raw material of animal origin for non-food use. Medical devices are subject to specific transport and labeling requirements.

The material has to be sourced from approved plants and the process has to be documented. For more information, please contact the Foreign Agricultural Service at the U.S. Mission to the European Union.

Environmental Requirements

Growing mountains of waste of electrical and electronic equipment have forced the EU to consider ways to reduce, recover and recycle packaging and appliances. Also, the use of hazardous substances has led to environmental damages; therefore, certain substances such as lead or mercury have been banned. Those issues have been tackled by the Waste of Electrical and Electronic Equipment Directive (WEEE) and the Restriction of Hazardous Substances in Electrical and Electronic Equipment Directive (RoHS).

Medical devices will fall under the scope of the RoHS directive in the future (3 years after entry into force of the text for medical devices, 5 years after entry into force of the text for IVDs). Others laws such as the Waste Electrical and Electronic Equipment (WEEE) directive require OEMs to dispose of products they manufacture in an environmentally responsible way once the equipment reaches end of life. Medical devices are covered by this directive but with a specific exemption today for "implanted and infected medical devices."

For more information, please visit ***export.gov/europeanunion/weeerohs***.

Chemical Substances and Mixtures in Medical Devices

Medical devices containing or consisting of chemical substances and mixtures are subject to specific requirements under the Registration, Evaluation, Authorization and Restrictions of Chemicals (REACH) Regulation and the Classification, Labeling and Packaging of substances and mixtures (CLP) Regulation. REACH entered into force on June 1st, 2007. It changes the former legislative framework for chemicals to ensure a high level of protection of human health and the environment. REACH makes industry responsible for assessing and managing the risks posed by chemicals and providing appropriate safety information to their users. Under REACH, the EU can also take measures to ban the use of highly dangerous substances. CLP aligns previous EU legislation on classification, labeling and packaging of chemicals to the UN GHS (Globally Harmonized System of Classification and Labeling of Chemicals).

Finland

Summary

High quality and technically sophisticated medical equipment has market potential in Finland. The United States has a 25 percent share of the total market. Finland also produces high technology medical equipment. Increasing competition in the marketplace is expected as local production expands.

Market Entry

Finland joined the European Union (EU) in 1995. As a member of the EU, Finland's local legislation concerning medical devices complies with EU directives. For more information, please visit ***valvira.fi/en/licensing/medical_devices*** or ***ec.europa.eu/enterprise/sectors/medical-devices/index_en.htm***.

Medical trade is duty-free within the European Union. Import duties are collected from production coming from non-EU countries. The amount of duty for medical equipment exported from the United States fluctuates according to a specific product, ranging from 5-12 percent.

Current Market Trends

In Finland, the total market size for medical equipment is estimated at $900 million in 2011 by the Finnish Healthcare Technology Association. Total local production is estimated at $1.2 billion in 2011. The operating costs of Finnish hospitals have been reduced, and major hospital procurement is mainly replacing older equipment and buying some new. However, investments in new medical equipment within the private health care sector are expected to continue.

Finnish hospitals are very eager to try out new technology in the implementation of most modern treatment methods. Implementation of new technologies is effective, as Finnish medical personnel is very technology literate. Local distributors provide the market with equipment packages and maintenance programs.

Main Competitors

Local production for medical equipment is well known for its quality and high technology. It is concentrated in specialized sectors, such as dental equipment as well as specialized x-ray and IVD equipment. About 90 percent of local production is exported because of the small domestic market size.

Statistics

Capital:	Helsinki
Population:	5.3 million
GDP:	USD 245.10 billion (2010)
Currency:	Euro (€)
Languages:	Finnish (92%), Swedish (5.5%), Others (2.5%)

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82 percent of the medical equipment imported to Finland comes either from or through the European Union. Direct imports from the United States account for 8 percent; however, the total market share is 25 percent. Other important external supplier countries are Germany, the United Kingdom, France, Russia, Japan, and China.

Current Demand

High quality and technically sophisticated medical equipment has the best market potential in Finland, especially equipment that increases efficiency and reduces occupancy rates in hospitals. Products such as these have the best sales potential in Finland:

- Patient monitoring systems
- Mini invasive surgery (MIS)
- Day surgery equipment
- Magnetic resonance imaging (MRI) equipment
- Video endoscopes
- Digital image processing
- Picture archiving

Barriers

There are no restrictions on imports in Finland, as long as they comply with EU qualifications. Although marketing requires thorough knowledge of end user needs, the import climate is receptive to equipment that is new and of good quality. There is keen competition in the market, however.

Trade Events

Finnish Dental Congress and Exhibition

Helsinki • ***web.finnexpo.fi/Sites1/Hammaslaakaripaivat/en***
Finland's leading event for dentistry professionals.

The Finnish Medical Convention and Exhibition

Helsinki • ***web.finnexpo.fi/Sites1/Laakaripaivat/en***
Finland's leading event offering further training for doctors and physicians. Concurrent with Finland's biggest medical exhibition.

Available Market Research

- Dental Industry Overview (2011)
- Medical Industry Overview (2010)

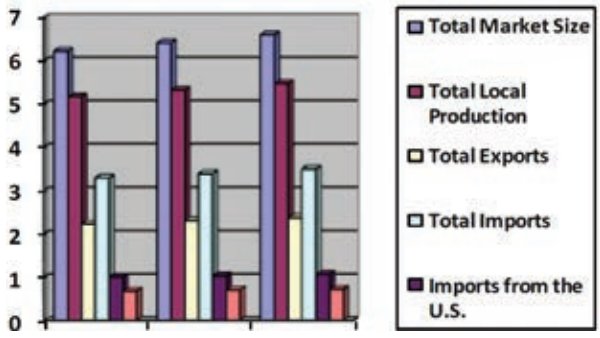
France

Summary

Total market demand in France for medical equipment was estimated at USD 6,784 million in 2012, with imports accounting for USD 3,592 million. Imports from the United States were forecast at USD 1,094 million, or 30 percent of total imports. This percentage is expected to remain approximately the same over the next three years, with overall demand growing at 3 percent annuallyy.

France Imports of Medical Devices, 2010–2012 (in USD billions)			
	2010	2011	2012
Total Market Size	6.4	6.587	6.784
Total Local Production	5.31	5.469	5.633
Total Exports	2.3	2.37	2.441
Total Imports	3.39	3.488	3.592
Imports from the U.S.	1.03	1.063	1.094
Exchange Rate (to USD)	0.699	0.72	0.7

France ranks among the top five largest medical device markets in the world. France spends 3% of total health expenditure on medical equipment and supplies and 0.3% of GDP, which is average for a West European country.



While the overall market is generally well developed, certain sub-sectors in the more innovative forms of technology still present opportunities for entry.

While the public sector is the largest purchaser of diagnostic, therapeutic and surgical equipment, the private sector is also a very dynamic player.

The continuing deficit of the national health insurance funds has prompted new measures to control spending on medical devices, similar to those already in force for pharmaceuticals.

Market Entry

To export medical devices to France, a foreign producer should have an agent/ distributor.

Statistics

Capital: Paris
Population: 67 million
GDP: USD 2.52 billion
Currency: Euro (€)
Language: French

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Medical devices in the French market, whether\ for imported products or domestically manufactured lines, are subject to the following requirements:

- Medical devices have to obtain the CE mark.
- Medical devices have to have Directions for use enclosed in the French.

Current Market Trends

The medical market is likely to see moderate growth, rising from USD 6.784 billion in 2012 to USD 7.8 billion by 2017. Foreign companies are prominent in the domestic medical manufacturing industry, with larger manufacturers operating as subsidiaries of multinational groups. With flagging domestic production in several sectors the French medical device market is increasingly reliant upon imports, which now account for around 50% of consumption.

Main Competitors

France is home to many subsidiaries of American companies such as Alcon, 3M, Baxter, Johnson & Johnson medical, Medtronic, Boston Scientific, Cyberonics and St. Jude Medical.

Current Demand

- **Diagnosis:** The diagnostic sub-sector represents 35 percent of the total medical equipment market. State-of-the-art diagnostic medical imaging systems are in great demand. Applications for this technology already exist for pediatrics, cardio-vascular care, digestion, urology, and spinal/nerve treatment. As it is well accepted and effective, the demand for this type of technology will continue to grow. Health care professionals are very optimistic about a feature of medical imagery equipment known as "image networking." This will dramatically improve diagnostics by providing an image data bank that would enable a specialist to compare the image of a current case to hundreds of previous cases.
- **Rehabilitation:** This sub-sector represents 26 percent of the total medical equipment market. It includes all types of disposable medical products. The increasing elderly population reinforces the demand for all kinds of disposable equipment and supplies such as incontinence products and care kits used by nurses and families for home-care.
- **Surgery:** The surgery instrument and supplies sub-sectors represent approximately 17 percent of the total sector. Recent developments in the non-invasive surgery field could have a strong impact on everyday hospital practice. These latest advances offer superior results and also present a significantly reduced risk to patients.
- **Technical aids:** The French market for medical prosthesis, 8 percent of the total medical equipment market, is characterized by a strong potential for innovative internal prosthesis such as knees, hips, ligaments, and elbows, and with a slightly decreasing market for external prosthesis. Technological evolution, especially in the field of anesthesia, offers the potential for rapid changes in this market.
- **Intensive care:** Intensive care equipment such as respiratory monitoring, pumps and incubators represent about 8 percent of the total medical equipment market. Intensive care equipment includes the latest technological advances. Both public and private hospitals show a rising demand for intensive care equipment and supplies.
- **Hygiene:** The hygiene sub-sector represents approximately 6 percent of the total medical equipment sector. Patient and medical personnel safety is of growing concern to members of the medical profession and the public. Best sales prospects will certainly focus around assuring stringent personnel safety requirements. This is especially due to the requirements considering the current concerns regarding infectious diseases. In the future, prevention should receive similar emphasis considering the present focus on protection.

Registration Process

All medical devices sold in France have to carry the CE Mark. Registering with the French Ministry of Health is to be addressed on a case by case basis. In the very best interest of any U.S. exporter, and in the vast majority of cases, this task is handled by the importer/distributor.

Barriers

There are no significant barriers on healthcare products in France.

Trade Events

HOPITAL EXPO

May 28–30, 2013 • Paris • ***hopitalexpo.com***

The largest medical trade show in France. 750 exhibitors and 24,000 visitors from throughout Europe.

Available Market Research

- In Vitro Diagnostics (2006)
- Medical Device (2009)

Germany

Summary

Medical technology is set to remain a German domain, at least until 2020. The trend report published by the Association for Electrical, Electronic and Information Technologies (VDE, Frankfurt am Main) for 2011, for which some 1,300 member companies and universities were surveyed, shows that Germany is the most innovative country in this field by a long way. This international comparison reveals the great importance of medical technology in Germany, especially against the backdrop of a dynamic and growing global health market and increasing competition between manufacturers.

Latest OECD Health figures report that the healthcare industry generated 11.6% of GDP (2010) in Germany. Approx. 5.4 million, or 12% of all employees, work in the healthcare sector, ten times more than in the chemical industry, making the healthcare industry the largest employer in Germany. Almost one in seven jobs in German is in the healthcare industry and the Federal Ministry of Economics anticipates that by 2030 an additional 2 million people will be employed in the industry. Health expenditures in Germany increased in 2010 by 2.6% to a total of $365 billion. Medical technology companies grew sales by 5.3%. Each German incurs healthcare expenditures of $4,338 annually.

According to the German Medical Technology Association (BVMed), the medical devices segment employed 175,000 and generated expenditures of $33.4 billion in 2011.

German Medical Equipment Market, 2011–2013 (in USD millions)

	2011	2012 (estimated)	2013 (estimated)
Total Market Size	30,000,000	32,000,000	33,400,000
Total Local Production	30,000,000	32,000,000	33,400,000
Total Exports	19000	20000	21000
Total Imports	18800	20000	21100
Imports from the U.S.	5307	5625	5906

Major barriers to local market expansion are ongoing health reform efforts and cost-containment measures. Demand will mainly be driven by demographics and a substantial increase in the number of patients; by the need for economies of scale and efficient procedures; and by a major investment backlog estimated at $61.5 billion in hospitals. In 2011, German states provided $3.56 billion in investment funding, $267.37 million less than in 2011 and 20% less than the previous ten-year average. This backlog especially affected the segments

Statistics

Capital: Berlin
Population: 81.77 million (2011)
GDP: USD 3.577 trillion (2011)
Currency: Euro (€)
Language: German

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surgery where, according to an employee poll, 56% of the equipment needs to be modernized/replaced, followed by internal medicine with 51%, and radiology with 50%.

More than two thirds of German physicians are seeing innovation as the key element in maintaining the high standards of the German healthcare system. Industry experts characterize the medical device market as dynamic with high growth potential and continuing consolidation, making it a highly attractive market for investors, despite the crisis. It will also continue to provide excellent potential for U.S. suppliers of innovative and price-competitive products. U.S. medical device exporters to Germany continue to hold a 27-30% in import market share, depending on the product category.

For general statistical information on Germany, please visit ***destatis.de*** and type "pocketbook" in the search line. This information is published by the German Federal Statistics Office.

Market Entry

Distribution Practices

Local representation or market presence is essential, when considering differing standards and certifications, warehousing costs, maintenance, accessibility and local marketing/sales preferences/ discussions. An agency agreement is often a cost effective mechanism to enter the market, but under German law it can be difficult and costly to terminate the arrangement—even if the agent's performance is not satisfactory. A representation or distributorship agreement may be harder to arrange but the German associate will, in fact, purchase the product which is to be sold, thus sharing the marketing risk.

In addition to complying with standards and regulations, U.S. firms should seek to meet some additional criteria to assure product acceptance recognition and marketability when trying to enter the German market. For example, they should supply product information and trade literature in German. At a minimum, catalog inserts should be in German. Firms should also provide operation and instruction manuals in German to insure proper understanding and usage of equipment, as well as providing reliable after-sales servicing and product support or select qualified agents or distributors who are capable of providing quality service. U.S. firms should maintain close contact and good feedback with agents in Germany in order to stay informed about market developments, trade issues, regulations, and laws concerning their products.

Product Standards

The German market for medical devices is regulated by German and European Union (EU) directives, standards, and safety regulations. The requirements are complex and based on environmental, consumer health, safety and social concerns. Not all standards and regulations are mandatory, but compliance greatly enhances a product's marketability. Advice on the requirements and compliance certification in the case of a specific product should be sought from the sources referenced below.

The German Medical Products Law (MPG) of 1995 underwent a fourth revision in March 2010. It applies to all equipment, instruments, devices, and materials, which are used on or in the human body and is relevant when trying to get permission to enter the German market. Exceptions are those devices, which achieve their intended effect pharmacologically. About 400,000 different medical products fall under this legislation. The MPG implements EU guidelines covering medical and diagnostic products. Devices complying with the MPG or its equivalent directives in other EU countries must carry the CE mark. They have the advantage of being permitted on the market anywhere in the EU without further certification requirements.

Packaging and Labeling

The European Union does not legislate packaging and labeling requirements in general, only in very specific high-risk product related cases. In the absence of any EU-wide rules, the exporter has to consult national rules or inquire about voluntary agreements among forwarders, which affect packaging and labeling of containers and outer packaging. The importer or freight forwarder is the first point of contact for shipping documents and outer packaging/labeling. EU customs legislation only regulates administrative procedures, such as type of certificate and the mention of rule of origin on the customs forms and shipping documents.

Product specific packaging and labeling requirements applicable throughout the EU apply to food, medicines, chemicals, pharmaceuticals, and other high-risk items. The purpose of harmonizing such legislation throughout the EU is to minimize the consumer risk. The relevant paragraph from the medical device legislation describes that the label must bear the following:

1. The name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of either the person responsible referred to in Article 14,
2. Or of the authorized representative of the manufacturer established within the Community or of the importer established within the Community, as appropriate;
3. The details strictly necessary for the user to identify the device and the contents of the packaging;
4. Where appropriate, the word "STERILE";
5. Where appropriate, the batch code, preceded by the word "LOT", or the serial number;
6. Where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month;
7. Where appropriate, an indication that the device is for single use;
8. If the device is custom-made, the words "custom-made device";
9. If the device is intended for clinical investigations, the words "exclusively for clinical investigations";
10. Any special storage and/or handling conditions;
11. Any special operating instructions;
12. Any warnings and/or precautions to take;
13. Year of manufacture for active devices other than those covered by (e). This indication may be included in the batch or serial number;
14. Where applicable, method of sterilization.

Payment & Fincancing Practices

In Germany the period allowed for payment is between 30 and 60 days. Early payments are credited with a 3% discount, and supplier credits are common.

Practices regarding financing, availability of capital, and payment schedules are comparable to those in the United States. There are no restrictions or barriers on the movement of capital, foreign exchange earnings, or dividends. Virtually all major U.S. banks are represented in the German market, principally (but not exclusively) in the city of Frankfurt/Main, Germany's financial hub. Similarly, a large number of German banks, including some of the partially state-owned regional banks, maintain subsidiaries, branches and/or branch offices in the United States. Germany is not eligible for support from OPIC, TDA or similar agencies.

Tariffs, Import Regulation

There is an import duty of 5.1% to 5.3% of the import product value along with a 19% import turnover tax payable at the port entry. For customs clearance, a product description is required describing the use, origin and value of the product. The cost of the import-turnover tax is usually offset by ultimately passing it on to the end-user in later distribution stages in the form of a Value-Added-Tax (VAT), known in Germany as Mehrwertsteuer (MwSt).

Current Market Trends

Major barriers to local market expansion are ongoing health reform efforts and cost-containment measures. Demand will mainly be driven by demographics and a substantial increase in the number of patients; by the need for economies of scale and efficient procedures; and by a major investment backlog estimated at $31.8 billion in hospitals and $3.2 billion in doctors' practices.

This backlog particularly affected surgery equipment. According to an employee poll, 56% of the equipment needs to be modernized and/or replaced, followed by internal medicine with 51%, and radiology with 50%.

More than two thirds of German physicians are seeing innovation as the key element in maintaining the high standards of the German healthcare system. Industry experts characterize the medical device market as dynamic, with high growth and continuing consolidation, making it highly attractive for investors, despite of the crisis. It will also continue to provide excellent potential for U.S. suppliers of innovative and price-competitive products. U.S. medical device exporters to Germany continue to hold a 28-30% in import market share, depending on product.

Main Competitors

The German market for medical devices is sophisticated and well served. Industry giants such as Siemens (Ger), Fresenius (Ger), Philips (NL), Hitachi (Japan) and Toshiba (Japan) are well entrenched. GE Medical, Agilent, 3M Medica, Hollister, and Johnson &Johnson are only a few of the many German subsidiaries of U.S. medical device suppliers. Despite this, the sector is characterized by small and heterogeneous companies or sub-groups of larger companies and rarely does one company represent more than 2% of the entire sector. In 2009 German manufacturers produced medical technology ranging from blood volume monitors to dental elevators. They had a total of over 400,000 devices, generating sales of $34.2 billion with an increase of 2.1% in domestic sales. Germany registered $16.3 billion in export sales, which increased 8.1% compared to the previous year.

Germany has to cover almost two-thirds of its demand for electro-medical equipment by imports. Even with a preference for locally produced products, American products can usually compete strongly on the basis of price and innovation. The United States is one of the major suppliers of medical devices to Germany and new and innovative devices are often reported very favorably upon in German media. For example, MA-based Carestream Health (formerly Eastman Kodak), a recipient of the Frost&Sullivan 2010 Medical Imaging Company of the Year Award, and provider of digital medical solutions, recently signed a partnership for a Center of Excellence program with the University of Frankfurt's Department of Diagnostic and Interventional Radiology, widely reported upon in the German medical press.

Current Demand

There is a stable demand for high-quality advanced diagnostic and therapeutic equipment, innovative technologies and minimally invasive equipment, in vascular surgery, urology, gastrology sand gastro-enterology sand gastro-enterology, dermatology, and neuro-surgery. Germany is proactive in coming up with solutions to address the aging population. Therefore, there will be an uptake in demand for diagnostic equipment to detect chronic diseases in their early stages in order to prevent higher costs. It

will also spur the demand for specialized wound care and easy-to-use home care products for diabetes, orthopedic appliances, and dialysis equipment.

The trend is toward miniaturization of electro-medical equipment and nanotechnology products. New technologies in emergency and first responder care along with computer-assisted surgery are widely discussed among the German medical community. German companies generate about a third of their sales with products that are no more than 3 years old and approximately 9% of their sales are reinvested in research.

As public insurance funds (the reimbursers of medical devices) continue to record deficits, cost containment will remain a priority. Thus, price-competitive state-of-the-art technologies and equipment offering proven cost savings will have strong market potential.

Registration Process

The CE Mark signifies that a product fulfills all necessary EU requirements. CE marking is now a legal requirement for a wide range of equipment manufacturers in Germany. Certification requirements for use of the CE mark vary depending on the product. For some, such as those in the MPG low risk class I, the manufacturers (or importer/ authorized representative, if the product is manufactured outside the EU) may self- certify compliance with EU requirements and affix the mark; for others the certification of a "notified body" (an accredited certification agency such as the TUEV) will be required. For the medical aids sector, the workability and safety of a product is now considered satisfied by CE marking. The CE mark is a visible indication that the manufacturer signed a "Declaration of Conformity" prior to affixing the CE mark, claiming compliance with all relevant CE marking directives in force.

All electro-medical equipment in Germany must be suitable for use with 220 Volt, 50 cycle electrical current, and should have VDE or TUEV approval. A UL approval is not a substitute but is helpful to obtain "GS/VDE", or GS/TUEV" approval in Germany. "GS" stands for "gepruefte Sicherheit" (safety tested). Although "GS" and the "VDE" (or "GS and TUV") marks are not required by law, they are highly recommended for marketing electro-medical goods in Germany. These labels denote high product safety; German consumers look for these labels as Americans do for the "UL" mark.

The U.S. Product Safety Testing Institute, Underwriters Laboratories (UL), the VDE Testing and Certification Institute, and the TUEV Product Service, have formed a strategic alliance for testing of electromagnetic compatibility (EMC) which has resulted in globally recognized EMC test mark. For manufacturers of electrical and electronic products, this cooperation has led to a substantive simplification of EMC testing. Through a single test carried out by one of these three partners, a product can now be awarded an international EMC mark, which replaces the national test marks in the major world markets of Europe, the USA and Japan.

Barriers

Firms exporting medical devices to Germany will not encounter any direct trade barriers or quotas. Non-tariff, indirect trade barriers could include the complex German reimbursement system, the need for additional registration procedures in the case of medical assistive technologies, for example, or products sold in pharmacies, with the requirement to apply for HMV or PZN codes, respectively. For Class 2 medical products, the German medical products law requires manufacturing and distribution control/ quality control documentation.

Trade Events

MEDICA with Compamed

November 14–17, 2012; November 20–23, 2013 • Düsseldorf, Germany • ***medica.de*** • ***compamed-tradefair.com***
Considered the world's most important and largest international fair for medical equipment, the annual MEDICA draws 140,000 trade visitors from more than 100 countries and over 4,500 exhibitors from 80 countries.

Rehacare

October 10–13, 2012; October 25–28, 2013 • Düsseldorf, Germany • ***rehacare.de***
Europe's premier rehabilitation and care event, open to the public and featuring many new products and developments. 50,000 visitors and 805 exhibitors from 32 countries.

Orthopädie + Rehatechnik

May 2014 • Leipzig, Germany • ***ot-leipzig.de***
The orthopedic and rehabilitation industry's leading event worldwide, with 21,200 visitors from 108 countries and 554 exhibitors from 45 countries. Biennial; features innovations and new products, as well as professional training.

BIOTECHNICA 2013

October 8–10, 2013 • Hanover, Germany • ***biotechnica.de***
The premier European biotech industry event, including sectors ranging from basic biotechnology and equipment, bio-informatics, and services to pharmaceuticals/medicine, industry, food, agriculture, the chemical industry, and the environment

A+A 2013 (Safety + Health at the Workplace)

November 5–8, 2013 • Düsseldorf, Germany • ***aplusa-online.de***
Attracts over 55,000 trade visitors and over 1,500 exhibitors. Covers all manner of safety and security equipment, technology, and processes.

FIBO 2013

April 11–14, 2013 • Cologne, Germany • ***fibo.de/en***
Europe's leading market platform for the fitness and wellness industry.

International Dental Show

March 12–16, 2013 • Cologne, Germany • ***english.ids-cologne.de***
Products and technologies for dental practices, dental labs, and specialized dentistry fields.

Available Market Research

- IVD Diagnostics 2011
- Nursing Care Market 2011
- Diabetes Market 2010
- Pharmaceuticals 2010
- Biotechnology 2010
- BVMED Annual Report 2011/2012
- Customized market analysis available upon request (fee required)

Greece

Summary

Greece's geographic location makes the country an excellent business gateway into Southeastern Europe. The continuously growing demand for medical equipment in Greece, as well as in many of the developing Balkan states, provides strong prospects for companies in the medical equipment field in Greece and neighboring Balkan countries. The Greek market for medical equipment has experienced stable annual growth of 12.7 percent over the past several years. One of the prime characteristics of this market is its high level of imports.

The economic developments in Greece, triggered by the recent financial crisis, created a new environment for all sectors. Initially, GDP in Greece was estimated at $381.3 billion, with a slight decrease of 0.3 percent for 2010. However, due to the developments related to the upward revision of the deficit and the bail-out of the Greek economy by the E.U., the IMF and the E.C.B. (the "troika") via the implementation of severe austerity measures, the latest GDP estimates show a sharp decline of approximately 4 percent. The Greek government, elected in October 2009, set as a primary target the reduction of the deficit by cutting waste and government spending, a target which remained a focus for the provisional coalition government appointed at the end of 2011. This has also impacted the public healthcare sector that is saddled with large debt accrued over several years. Countering this is an ever-growing private healthcare system that is well represented by U.S. firms and continues to provide opportunities for American companies. Industry executives believe that the Greek financial crisis can become an opportunity to promote reforms in healthcare that will benefit both the patients and the key players of the industry.

On May 6th, 2012, the general election resulted a highly fragmented parliament. Thus, a new election took place on June 17th, 2012, leading to the formation of a coalition government between a centre-right and two left-leaning parties. According to the newly appointed Minister of Health, Lykourentzos, one of the main goals for 2012 is for the government to reduce its spending for pharmaceuticals by 1 billion Euros.

The Greek GDP is expected to be around US$318.6 billion in 2011, with a 1.6% fall predicted for the coming year. The economy is not predicted to grow until 2013.

According to the Ministry of Health and Social Solidarity, Greece spent over nine percent of its total GDP of $343.6 billion on healthcare in 2009. This is due to the implementation of a structured plan by the state to further increase the quantity and quality of healthcare services provided, particularly to regional areas of Greece, and the need of the private sector to stay competitive (90 percent of

Statistics

Capital:	Athens
Population:	11 million (est. 2010)
GDP:	USD 318.6 billion (est. 2011)
Currency:	Euro (€)
Language:	Greek

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the private sector's expenditures are for high technology medical devices). Meanwhile, the government is trying to increase the use of generic drugs from 18 percent to 50 percent.

Healthcare expenditures as a share of GDP in Greece are about 10 percent or $3,092 per capita annually. This expenditure is comprised of 52 percent government–provided care and 48 percent private care. Preference for private healthcare has been higher in Greece than in most E.U. countries during the recent years, although this is changing, given the economic situation and Greek citizens' ability to pay for private care.

Market Entry

As a member of the E.U., Greece applies the E.U. common tariff schedule on products imported from non-E.U. countries. All products, regardless of origin, are subject to the value-added tax (VAT) which as of July 1, 2010 is 23 percent for most products (compared to the previous 21 percent rate) and 11 percent for pharmaceutical products. A further increase is under debate, as a result of the government's intention to raise more funds to fight the budget deficit.

Medical Equipment & Devices Sectors

While duties are applied to parts of medical products and disposables, U.S. medical equipment receive duty-free treatment. Within the E.U., medical device legislation has been harmonized through the European Union's Medical Devices Directive 93/42/EEC. This enables a manufacturer who has approval in one E.U. country, to gain access to Europe's entire market without having to obtain approvals from each additional country. All low risk devices, which are in conformity with the requirements of the directive, must carry a CE mark. Higher risk classified products, in addition to the CE mark, must carry the identification number of the certifying organization that performed the conformity assessment and issued the approval. National implementation of the Medical Device Directive requires instructions for use in the national language. However, technical manuals and promotional material may be in English, French or German. Representatives in Greece can assist U.S. companies to meet these standards, if the U.S. firms have not already done so, in an effort to enable them to gain access to E.U.'s entire market.

OTC & Dietary Supplements Sectors

All the details pertaining to the introduction of a new food supplement to the Greek market are outlined in the Greek Government Gazette #935 of November 13-1995 and in the E.U. Directive 2002/46/EC of the European Parliament. An American company interested in entering the Greek market is advised to find a local agent/distributor in order to expedite procedure normally encountered during the registration-approval process.

In 2012, a plan to merge the National Organization for Medicines with the Hellenic Food Authority and other similar organizations was proposed to the Greek government by appointed consultants. The new centralized agency will have similar responsibilities to the U.S. FDA, making the regulatory process faster.

Current Market Trends

Medical Equipment & Devices Sectors

The Greek market for medical equipment was estimated in 2010 to have increased by 5.4 percent compared to the previous year. It is estimated that the Greek market for medical equipment in 2010 reached $1,569 million, out of which around 95 percent was supplied by imports. The greater share of the companies' revenues is recorded in their business with the public sector (at around 80 percent) but this slightly changed due to the revised company focus toward the private healthcare sector, given its ability to pay for the products it buys in a reasonable time frame. As of 2012, approximately 13,000 individuals are employed in the Greek pharmaceutical and medical supplies fields.

Health IT Sector

Health Information Technologies (e-Health) consists of hardware and software systems used by healthcare professionals to gather, file, classify, have access to, and electronically exchange healthcare information including administrative, clinical and other supportive systems. In terms of e-Health, Greece scores below the E.U. 27 average regarding availability of Information and Communication Technology (ICT) infrastructure (computers and Internet) and the use of ICT for e-Health purposes. Although Greece was lagging behind the E.U. in internet penetration and broadband, the aim of the National Digital Strategy was to reach the E.U. average by 2010, and the recent government efforts through its National Digital Strategy (2006-2013), including related investments of over $665 million have already led to considerable improvement. In particular, Greece is quickly catching up to the above-mentioned E.U. average (20 percent). As of October 2009, the overall broadband penetration reached 16 percent of the population (almost 2 million broadband connections), which is a 44 percent increase from the previous year and a great improvement compared to the 0.2 percent in 2004.

Although the use of ICT technology for use in healthcare appeared in the 1980's, ICT solutions have not yet been strongly adopted in healthcare practice in Greece. This is mainly due to the rather late development of an e-Health strategy. The national road-map that was drafted in 2006 calls for the creation of a National Health Information System. Pilot programs are planned for the 2007-2015 period.

Therefore, the required infrastructure, including standards, a national health portal, insurance smart cards, electronic information systems, etc., will start becoming available in the upcoming years. As a result, there are not many available on-line health services, either public or private. In terms of infrastructure, in 2007, 79 percent of general practitioners were using a computer, those with an Internet connection were measured at 66 percent, and 44 percent had a broadband connection. This compares to an average of 87 percent, 87 percent and 79 percent, respectively in the E.U.27 countries. Moreover, in 2009, 79.4 percent of Greek physicians started using computers to create electronic patient records, where the E.U. 27 equivalent percentage is 87.5 percent.

For years, Greek physicians used hand written prescriptions. However, the Greek government is pushing for the immediate adoption of the online prescription program. This program requires the modernization of the health-care e-system and the use of IT to monitor the drugs prescribed.

OTC & Dietary Supplements Sectors

The OTC healthcare market in Greece is characterized by consolidation of global supplies, with multiple foreign brands active in the market. This market condition does not seem likely to change, as multinationals are only becoming stronger and traditional Greek firms are moving towards importing rather than manufacturing medicines. The trend of health and wellness in Greece has favored companies in nutritionals, herbal/traditional products and in OTC healthcare, for example vitamins and dietary supplements.

Local production of pharmaceuticals and vitamins in Greece has been declining for several years, while imports are constantly increasing. However, strong competition among the multinationals makes it difficult for smaller companies to develop and maintain a considerable market share. Financially robust firms rely heavily on advertising to carve out their market share.

The Greek vitamin and dietary supplement market has grown significantly during the last decade, creating investment opportunities. It is indicative that the market for OTC healthcare in Greece increased between 2001 and 2006, growing at an average annual rate of 5.9 percent. There was a decline in market demand in 2010 to be expected based on the recent economic crisis that Greece is experiencing and the decline in purchasing power.

In the last decade, the consumption of vitamins and dietary supplements has increased as people learn of potential beneficial effects through advertisements and their doctors.

Main Competitors

In the Greek market, there are approximately 300 active companies in the medical device field. These companies are mainly importers and distributors of scientific and medical equipment which also provide after-sales services. Key suppliers of medical equipment to Greece are the United States, Germany, and Italy, and to a smaller degree, the Netherlands, France, United Kingdom, and Luxemburg. The E.U. has acquired a major share of the Greek market due to geographic proximity, product quality, established marketing arrangements and favorable tariff treatments. Domestic manufacturing in this sector is not highly developed. Consequently, the supply capability of Greek companies is largely limited to low-value products such as syringes, bandages, gauze and various small medical devices. The medical equipment

market in Greece is highly competitive because of the number of diverse importers. The structure of the public healthcare sector and especially the bureaucratic process of the existing tender system make it imperative for U.S. suppliers to have local partners. Competitive strategies focus mostly on pricing, exchange rates, and payment terms, particularly when dealing with the public hospitals. Leasing is also an option, especially for large, high-tech, expensive equipment. The most active and profitable sub-sectors for foreign suppliers include surgical equipment and supplies, electromedical equipment, IT healthcare systems and telemedicine technology. Specifically for IT healthcare, there is significant demand for products that increase the patient's safety through reduction of medical errors, while improving health information management.

Relevant U.S. company presence in the Greek market includes: 3M, Abbott, Alcon, Bard, Baxter, Boston Scientific Hellas, Carestream, Edwards Lifesciences, GE Medical Systems, Johnson & Johnson, Medtronic, Stryker, and Teleflex Medical. It should be noted that the actual share of U.S. imports was much higher than the estimated 18 percent because a large amount of the medical equipment was produced by the European subsidiaries of U.S. firms and are registered as having originated in the E.U.

Current Demand

In the past year alone, private care accounted for up to 48 percent of total health care expenditures, while the European average is around 27 percent. There are two major sources of demand for medical devices: (1) Public Health Institutions (hospitals, health centers, and regional clinics) and (2) Private Health Institutions (hospitals, clinics, diagnostic centers, and professionals). Demand from consumers represents a small but increasing segment of the market. Research shows that demand for medical equipment from public hospitals represents approximately 80 percent of the total demand, making public sector hospital payment delays a serious concern. In the medical equipment market, suppliers claimed delayed payments that amounted to $1.1billion. There are ongoing public and private initiatives to reduce the mismanagement of public capital and delay of payments, which the new government claims is at the top of its agenda.

The Government of Greece is evaluating new methods for maximizing public healthcare system efficiency and improving the services offered by public hospitals, while at the same time reducing the relevant budget. There are various plans under consideration by the government such as: the merging of many hospital units, twenty-four hour operation of all public hospitals, greater level of transparency in hospital financial transactions and in hospital procurement, and more efficient allocation of public healthcare system resources and human capital. Additionally the Greek government recently agreed to start paying off debt to hospital suppliers and to maintain the uninterrupted flow of medical supplies and consumables to public hospitals but this is still tentative.

The challenges within the public sector have created an opportunity for the private sector to grow in importance. The involvement of the private sector in health care delivery is extensive and has been growing rapidly since the early 1990s. The current number of private hospitals and clinics is 234 with a total capacity of 15,397 beds, a number that accounts for 26 percent of the total hospital beds in the country. Most of these facilities are general and maternity hospitals.

The market leaders in the private Healthcare Sector in Greece are the Athens Medical Group, Euromedica, Hygeia Group, and IASO Group. These medical business groups have grown tremendously from the past decade. These companies continuously seek to increase their stake in the market, however, because of the current economic situation, operate under financial pressure. Already, they have established facilities in Greece and some neighboring countries, such as Albania and Cyprus. The private health care sector is averaging an annual growth of 13-15 percent. General and diagnostic clinics have averaged 16.8 percent and 8.4 percent annual growth, respectively. However, a declining trend in private healthcare has appeared, mainly because of the current financial hardships within the country (tovima.gr). The demand for public hospitals has increased by 20-30 percent. In terms of primary health care, there are more than 25,000 private practitioners and laboratories, and approximately 250 diagnostic centers in Greece, most of which are equipped with, "big ticket" medical technology. Private practices,

labs and diagnostic centers are also contracted through social insurance funds to provide health care services to their beneficiaries. Remuneration is on a fee-for-service basis. Rehabilitation services and services for the elderly (geriatric homes, etc.) are predominantly offered through the private sector.

Barriers

There are no real barriers for entry in the Greek market. However, the situation with public sector hospital payment arrears has been an issue, particularly amidst the Greek economic crisis. Many companies have witnessed long delays in the payment of accumulated debts by the Greek public sector. However, the DIRECTIVE 2011/7/E.U. of the European Parliament and of the Council of 16 February 2011 on combating late payment in commercial transactions has placed some increased pressure on the Greek government in proceeding with the normalization of payments in the future. Despite this directive and given the financial crisis, there is new public sector debt accrued once again since 2011.

Registration Process

There is no requirement for an FDA certification, since it is not accepted by the EU legal framework. Every product must comply with European standards. Companies interested in exporting to Greece should apply through the importing company to the National Organization for Medicines (EOF), indicating the country and the laboratory that produced the pharmaceutical, as well as precise details about its active ingredient, etc. The company importing the U.S. pharmaceuticals should also have an EOF license to import pharmaceuticals. The exporter and/or the product should also be certified with the Good Manufacturing Practice (GMP) by a member state of the EU. This can be based on the Compilation of Community Procedures on Inspections and Exchange guidelines as described in the Outline of a Procedure for Coordinating the Verification of the GMP Status of Manufacturers in Third Countries. Additional documentation, such as the license to produce the pharmaceutical product by the FDA, should be provided. Relevant fees will be applied for the procedure.

There are no import restrictions for medical devices. However, there is a requirement for CE Certification (European Conformity) according to the European Law which can be provided by the authorities of any EU country and is accepted by the member countries of the EU. According to the Council Directive 93/42/EEC as amended by Directive 2007/47/EC, a manufacturer from a third country, who does not have a registered place of business in EU seeking a CE Certification should designate a single authorized representative in the European Union.

Trade Events

MedicExpo '12

Thessaloniki • ***medicexpo.com***

Available Market Research

- Medical Equipment Market 2010
- Health Information Technologies Market 2009

Guatemala

Summary

Present situation & outlook of the market

Guatemala is a country of over 13 million inhabitants with high levels of poverty that require assistance by the public sector for its health care needs and also a large number of inhabitants that do not use public services because they can afford a private hospital or clinic. The market for medical services is divided into two segments, the private and public sectors.

The private sector, as a common rule, purchases only well known brands of medical equipment because of their appreciation for high quality products and total customer support from the distributor in any emergency. Investments in new medical equipment within the private health care sector are expected to continue as new clinics and existing hospitals periodically make equipment purchases and continue to invest strongly in new diagnostic and treatment technology.

The Government, on the other hand, is price driven and will purchase from the lowest bidder via public tenders. All medical services in public hospitals and clinics are free of charge to any patient. This means major hospitals are replacing older equipment and buying new equipment that can meet the demand for free medical services for the whole population. The public sector consists of hospitals and clinics operated by the ministry of health through the social security institute and the armed forces.

According to data from the Central American Secretariat for Economic Integration (SIECA), Guatemala's total imports of medical devices, including reagents, amounted to USD110.5 million in 2011, an increase of 4.4% in relation to 2010. Imports of medical devices from the U.S. accounted for 37% of the amount imported in 2011.

Guatemala Imports of Medical Devices, 2009–2011 (in USD millions)

	2009	2010	2011
Total imports	104.5	105.8	110.5
Imports from the U.S.	39.3	38.4	41.1
U.S. share of imports	37.6%	36.3%	37.2%

Source: Central American Secretariat for Economic Integration

Statistics

Capital: Guatemala City
Population: 13,276,517
GDP: USD 74.709 billion
Currency: Quetzal (GTQ)
Language: Spanish

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Market Entry

The most important decision a U.S. company has to make is to choose a local representative. The best strategy is to screen potential importer-distributors, and select the most qualified.

The chosen importer should be a company that is registered to sell to the government and can participate in official tenders and bids. Also this company needs to know the private market and have constant communication with the purchase manager of Hospitals, clinics and medical doctors with practices that use machinery.

Once the exclusive representation is given to a Guatemalan importer it is difficult to take it back because of the representation law in Guatemala, so it is necessary to have a good relationship and chose the correct representative. The legal system can be slow and the law, under certain conditions, offers local agents a great deal of protection.

Formal agency or distribution agreements should be reviewed by a Guatemalan attorney hired by the U.S. exporter (independent of the Guatemalan party with which the agreement is being established).

Current Market Trends

Preferences of local consumers

The preference of hospitals and clinics for medical equipment is based mostly on:

- Brand name
- Specifications of the equipment
- After sales and training of the end user
- Latest technology or world trend
- Demand of differentiated markets

The final consumers or end users of the medical equipment are all the private and public hospitals and clinics in Guatemala. The difference between those markets is that private customers buy immediately and often look for the best brand of equipment; meanwhile public purchases are made by bids all year long and are informed by the Government via their website, ***guatecompras.gt***.

Main Competitors

There are many competing countries depending on the specifications and purpose of the equipment, but in general the United States of America is the most important exporter of medical equipment to Guatemala with an important share of the market. Germany is the second major exporter to Guatemala, but is showing a decrease in almost all the categories of HS code due to the high prices of the German brands and because they export their medical equipment through the U.S. because it is more convenient for delivery time. Japan and China are in third place depending on the HS code as each feature different prices and quality of their products.

Current Demand

The total number of hospitals in Guatemala is approximately 190 and the total number of clinics 2,482. There is no exact number for the private sector because there is no official record. The ministry of health only keeps records for the public sector.

All hospitals will need to purchase equipment in the future as a matter of course in the medical field so medical equipment like radiology, mammography, IMR, scanners, patient monitoring systems, digital image processing clinical laboratory equipment and dialysis equipment will be purchased periodically by all the hospitals and clinics in Guatemala depending on necessity.

Medical equipment is constantly evolving and utilizing sophisticated products. Most end users are looking for new technologies and prefer user-friendly features in the medical machines. Recently end users have also requested companies provide manuals, and instructions in Spanish as well as Spanish labeling of buttons on machines.

Registration Process

Most medical devices require sanitary registration at the registration office of the Ministry of Health. Some of those devices also require lab analysis from the National Health Laboratory.

The requirements for both procedures and the requirements for packing are listed under Technical Regulation No. 37-2003 of the Ministry of Health's Department for the Regulation and Control of Pharmaceutical and Related Products.

This technical regulation also provides a classified guide/list of medical devices that require sanitary registration and lab analysis.

According to the head of the Department for the Regulation and Control of Pharmaceutical and Related Products, the National Health Laboratory only conducts microbiological tests on sterile products and does not evaluate functionality/effectiveness of devices. She stated that sanitary registration processes are usually completed in about one week when lab tests are not required and in about six weeks when lab tests are necessary.

Sanitary registrations need to be renewed every five years. Devices such as anesthetics and asthmatic inhalers, high pressure measuring apparatus, laser-guided apparatus do not require sanitary registration at the Ministry of Health.

Barriers

There are no trade barriers for medical equipment from the U.S.

Trade Events

There are no fairs related to medical equipment but most importers travel once a year to the FIME Expo in Miami, FL (***fimeshow.com***) to network and seek out new products and trends.

Hungary

Summary

As in most European countries, Hungary's health care system is mostly state-funded. Hungary's long-term policy focuses on maintaining public but offer private health care services through privately-operated healthcare clinics and centers. The public sector accounts for about 80 percent of the total health expenditure. In 2011, Hungary spent 7.4 percent of its GDP on public healthcare, representing about USD 9.6 billion. Restructuring of the healthcare systems started in early 2011 when the government of Hungary came up with reform plans for renationalizing Hungarian hospitals that were maintained by the local government. The restructuring process had not been completed by the deadline which was the end of February 2012 and all healthcare-related public procurement procedures started with a six-month delay early September 2012.

Market Entry

Medical devices

In May 2004 Hungary joined the EU, and became part of the External Tariff System. According to Hungarian tax regulations, all products, regardless of origin are subject to an extremely high (27 percent) value added tax (as of April 2012), which is borne by the final customer (hospital or patient). The EU directives on Medical products have been integrated into Hungarian legislation. Generally, there must be one Authorized Representative in one of the EU countries, who is responsible fo the EU-wide CE mark. Prior to entering the Hungarian market, medical products must have the CE mark. If a medical product has the CE mark issued by an eligible notified body, no further testing is required by any Hungarian authority. If the product has no CE mark, a Hungarian notified body can issue it. According to Hungarian regulations, foreign suppliers are required to have a Resident Representative in the country responsible for the foreign product. This person registers the product with the Authority for Medical Devices (c/o Ministry of National Resources) and provides the necessary information including directions for use and labeling in Hungarian. The resident representative keeps the technical files and is the point of contact for market surveillance.

The Hungarian market is receptive to high quality U.S. medical equipment. As Hungarian health care system is widely felt to be under-financed, foreign companies have a competitive edge if they offer financing. Participation in seminars, medical exhibitions and scientific meetings is still an efficient tool of trade promotion in Hungary. Medical products are marketed in Hungary through authorized and exclusive distributors. Major foreign companies either have their own subsidiaries or operate through local distributors. Most

Statistics

Capital:	Budapest
Population:	9.9 million
GDP:	USD 13 billion
Currency:	Hungarian Forint (HUF)
Language:	Hungarian

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distributors handle several brands of similar equipment or several lines. Pricing is a key factor in selling a medical product in Hungary, as the market is very price sensitive. When purchasing medical equipment, end-users also look for established companies with reliable after-sales service and customer support.

Drugs

Registration of all medicines intended for human use including homeopathic preparations, preparations marked with isotopes and immune-biological preparations, vaccines and blood products is carried out by the National Institute for Quality and Organizational Development in Healthcare and Medicines (GYEMSZI) formerly National Institute of Pharmacy (OGYI).

Current Market Trends

Imports dominate the very competitive Hungarian market for medical supplies and equipment. About 82-85 percent of an estimated USD 795 million (2011) is spent on foreign products. According to the estimates of the Association of Medical Technology in Hungary, roughly 20 percent is spent on high-value devices, another 30 percent for rehabilitation products and the rest for medical equipment and hospital supplies.

Hungarian companies supply local products for about 15-18 percent of the medical equipment and supply market. There are 150-170 small and medium-sized medical companies in Hungary, most of them specialized in high-tech products for export markets and in R&D activities with a staff of less than 20 people. Electro-medical apparatus are the largest products by export value. Other companies manufacture medium to low-tech products mostly for the local medical market.

U.S. products account for approximately 10-15 percent of total medical product imports. In addition to the official statistics, a number of European subsidiaries of American companies are shipping products to Hungary registered as goods from Germany, the Netherlands, the U.K., etc. A few American companies have their own representative and sales offices in Hungary, while most distribute their products through local firms. Medical products imported from the U.S. in significant amounts include electro-medical instruments; disposables like catheters; ultrasound machines; electro-diagnostic devices; orthopedic appliances and implants, hearing aids and pacemakers.

Main Competitors

The import of medical products is fully liberalized. American companies face stiff competition from West European companies in Hungary. German, Austrian, Italian and British firms have been present for many years in the market. Germany has been the sales leader for decades with over 20 percent market share in the overall medical market. The proximity of the European firms to the Hungarian market allows them frequent visits to meet end users, to participate in exhibitions and scientific meetings, and to provide prompt after-sales services to buyers. Some of them have established manufacturing units in Hungary for serving their Central-Eastern European markets.

Current Demand

Medical Devices

Funding from EU structural fund has been used for priority healthcare development projects, including development of outpatient clinics (funds for 16 regional outpatient clinics has been approved), development of one-day surgery, development of high-priority hospitals for the regions, and upgrade of emergency care.

Opportunities for U.S. medical equipment suppliers include ultrasound equipment, digital X-ray, monitoring equipment, MR, CT, nuclear imaging (PET, Gamma camera), laboratory diagnostics, and clinical chemistry.

Dental Equipment and Supplies

With 5,500 practicing dentists (out of 6,000 registered), Hungary is a market leader in providing dental services for dental tourists. It has a market share of 42 percent, closely followed by Poland (31 percent), Turkey (15 percent), Spain and Bulgaria with 7 percent. The size of the Hungarian dental equipment and supply market is estimated to reach about USD 32 million. It is dominated by German, Scandinavian, Italian, French and Japanese suppliers however it provides market potential for U.S. suppliers of teeth whitening systems, lasers, optical instruments, implant instruments, root canal treatment, computer-controlled injection devices for anesthetization, and orthodontics devices.

E-Health

In the framework of the National Development Plan, European Funds are allocated to various healthcare expenditures including specific IT related projects. Best prospects include the E-Health Card, E-Patient Registration system project that will require the supply of about 40,000 card readers, a card management system, card application and authentication solutions etc. and the Electronic authentication database and healthcare portal project requiring security and authentication solutions.

Drugs & Pharmaceuticals

Drug sales amounted to USD 2.88 billion in 2011. Imported medicines accounted for 68 percent of sales, worth USD 1.9 billion. As of September 2011, there were 5,600 registered drugs on the Hungarian market, out of which 4,900 were prescription medications. In 2011, the number of subsidized drugs reached 5,250. The number of over-the-counter (OTC) medications rose to 1,380 in September 2011. In terms of total sales, prescription drugs dominate the market with approximately 85 percent of the market share. Four-hundred forty OTC products can be sold outside pharmacies in gas stations, drug stores and large hypermarkets as well. There is no import duty levied on pharmaceutical products, and a 5 percent VAT must be paid by consumers.

Barriers

Firms exporting medical devices to Hungary will not encounter any direct trade barriers or quotas. Non-tariff, indirect trade barriers, however, affect the pharmaceutical manufacturers including a 20 percent tax on reimbursed sales of pharmaceutical products, a non-proportional annual fee of HUF 10 million (about USD 54,000) for every pharmaceutical sales representative, and a claw-back, mandating that pharmaceutical manufacturers repay the Government for up to 100 percent of pharmaceutical over-expenditures by the National Health Insurance Fund (NHIF). In order to meet the requirement of the convergence plan and keep the budget deficit under 3 percent, the government plans a HUF 150 billion (USD 750 million) cut in the Pharmaceutical Fund over 3 years that seriously affects innovative pharmaceutical manufacturers in the market.

If there is an overspending in the pharmaceutical budget, the NHIF determines which pharmaceutical manufacturer's market share has increased compared to the base year. Any company whose turnover has exceeded the market share of the baseline year has to pay this claw-back on the basis of a complicated formula.

Trade Events

Dental World Budapest

Oct 11–13, 2012 • Budapest, Hungary • ***dentalworld.hu***

Available Market Research

- Dietary Supplements and Vitamin Market 2010
- Dental Equipment and Supplies Market 2010
- Clinical Trial Market 04/2010

India

Summary

The Indian healthcare industry is experiencing a rapid transformation. According to a World Health Report, India spends about 5.5 percent of its GDP on the healthcare sector which is expected to rise to 6.1 percent of GDP and employ around 9 million people by the end of 2012. The World Health Organization forecasts that India needs at least 80,000 hospital beds per year for the next five years to meet the expanding local demand. The Indian Healthcare industry is estimated at $56 billion (5.5% of India's GDP) and is expected to reach over $75 billion by 2012 and US$ 150 billion by 2017. The medical equipment market is growing at an impressive rate of 15 percent. Hospital facilities depend on the import of high-end medical equipment.

Market Entry

In India, healthcare is delivered through both the public sector and private sector. The private sector's contribution to healthcare has been growing at a faster pace than the government's. There are no restrictions on foreign direct investment in healthcare services. Import of medical equipment is allowed under the "Open General" category of the Import regulations, except for nuclear medicine. Customs duties levied on imported products depends on the product classification. For some devices the duty has been brought down from 25 to 5 percent. Products classified as "life saving equipment" have a reduced duty to encourage hospitals to import the latest equipment.

Price, quality and after-sales service support are major factors in medical equipment purchase decisions. Letter of credit is usually the mode of payment for imports. Purchase decisions by the government follows a time consuming tendering process while the process is faster in private hospitals.

Current Market Trends

The Indian population of 1.22 billion people is growing at a rate of 1.6 percent per year. The growth in affluence of over 400 million strong middle-income consumers is creating demand for a higher standard of healthcare. Many in the growing "middle income" segment look for international quality medical services in private super-specialty hospitals, and this trend is expected to continue for the next five years and beyond. According to a World Bank report, 79 percent of all outpatient care among the poor is provided by the private sector.

The number of lives covered by health plans is estimated at 20 million presently, leaving a large Indian population that needs to be insured. Healthcare insurance premium collections are growing steadily to reach $3.8 billion by 2012. With

Statistics

Capital:	New Delhi
Population:	1.22 billion
GDP:	$4.46 trillion (PPP)
Currency:	Indian Rupee (INR)
Language:	Hindi, English

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the private sector continuing to aggressively market healthcare insurance the healthcare industry is witnessing a change.

The type of healthcare service requirement has changed due to the change in demographic profile and rise of lifestyle-related diseases such as diabetes, cardiovascular diseases, and diseases of the central nervous system.

In India, healthcare is provided through primary care facilities and secondary and tertiary care hospitals. While the first two categories are fully managed by the government it is the tertiary care hospitals that are owned and managed either by the government or private sector. To meet growing demand, one million beds will be added by 2012 to bring the bed to thousand-population ratio to 1.85. The private sector's contribution to healthcare has been growing at a faster pace than government. The medical infrastructure market is estimated to have a growth rate of 15 percent. Both the government and private sector are planning new hospitals as well as the upgrade of existing hospitals. Corporations are sensing the huge untapped opportunity in delivery of quality healthcare to the Indian masses and focusing on tertiary-level preventive and diagnostic healthcare. The public sector is engaged in prevention and elimination of infectious diseases and accessibility of basic healthcare facilities to the rural masses. The National Rural Health Mission 2005-2020 aims to provide medical care to all rural Indians. Not only providers but also global PE and Venture funds are vying to explore opportunities.

The demand for medical equipments is expected to reach $5 billion by 2012 from the current figure of $2.7 billion. Imports account for over 65 percent of the entire medical equipment market, of which 85% is from US. The medical device market is becoming too big to ignore.

Medical Tourism is also fueling additional growth in the Indian healthcare sector. The cost of major surgeries in India is much less than the cost for the same surgery in a developed economy. Government and private sector estimates the value of this segment of the industry to reach $1.48 billion by 2012. The healthcare industry is now proactively creating standards for the medical tourism industry with the help of credit rating agencies, insurance companies and others involved in the self regulation of the sector.

Main Competitors

The large private healthcare services providers are actively seeking growth by enhancing their reach across the country through the building new hospitals and acquiring and upgrading existing hospitals. There are several groups operating hospital chains including Apollo Group, Fortis Healthcare, Manipal Group, Max Healthcare, Medanta-Medicity, and Wockhardt Hospitals. In the medical equipment segment competition is from the imports from European companies and Japan. With India being a price sensitive market, there is competition from low priced Chinese products.

Current Demand

The growing demand for quality healthcare and the absence of matching delivery mechanisms pose a challenge and certainly a great opportunity. In infrastructure, building, equipping, managing, and financing of hospitals are areas for growth. Some of the best sales prospects in the medical equipment market include medical and surgical instruments, medical imaging, electro medical equipment, orthopedic and prosthetic appliances, cancer diagnostic, ophthalmic instruments and appliances.

A proper supply of equipment and medical consumables will also be an area with significant opportunities for American companies. Several leading U.S. purveyors of hospital equipment and supplies have opened Indian operations to cater to this growing market.

Health insurance and hospital administration is another area in which U.S. companies can make a difference. The opportunities include introducing and maintaining industry standards, and also classifying and certifying healthcare centers.

The opportunity also exists for overseas organization building, equipping and managing super specialty hospitals in India through the FDI route is another area for future growth.

Other growth areas include diagnostic kits, reagents and hand-held equipment. Imports constitute 50 percent of this market. Hand-held/portable diagnostic equipment (e.g. for blood sugar, blood pressure testing etc) is also a fast growing segment since India has around 45 million diabetics.

Registration Process

The Central Drugs Standard Control Organization (CDSCO) is the key regulatory organization in India. Import of medical devices into India still remains largely unregulated though the Indian government has adopted some measures in recent years to change that. With the final procedures and guidelines not being laid down as yet, things are actually pretty confusing at this stage. Currently, Ministry of Health and Family Welfare, Government of India has notified only 14 devices that are regulated. Attached visit ***cdsco.nic.in/Medical_div/list%20of%20notified%20medical%20device.0001.pdf*** for a list of the 14 regulated medical devices

Please visit ***cdsco.nic.in/Medical_div/medical_device_division.htm*** for more information on import regulations and registration process.

The CDSCO drug controller contact information is available at ***cdsco.nic.in/html/contactus.html***. Please write to CDSCO office for detailed information on medical device import regulations and registration requirements.

Barriers

To ensure quality healthcare in October 2005, the Government of India (GOI) increased the list of medical devices covered under the Drugs and Cosmetics Act of 1940, bringing fourteen categories of implantable devices under regulatory control. These include stents, heart valves, catheters, intra-ocular lenses, hip and knee implants and bone cements, I.V. Cannulae, in vitro diagnostic devices. An improved central licensing authority must license these devices for manufacture, sale or distribution. Hospitals are also seeking quality accreditations like JCI, NABH and ISO. The authority regulating medical devices, Central Drug Standard Control Organization, has listed devices for regulation at ***cdsco.nic.in***. The Indian government has identified healthcare as a priority sector.

Trade Events

World Dental Show

October 5–7, 2012 • Mumbai, India • ***wds.org.in***
Dental technology and dentistry.

Medical Fair India

March 8–10, 2013 • New Delhi, India • ***medicalfair-india.com***
Medical/healthcare sector.

Indonesia

Summary

Given the large population and steady economic growth, Indonesia presents excellent opportunities for U.S. companies. An increase in public awareness about the importance of healthcare, the expansion of public and private hospitals, and the government's plan to implement universal health insurance coverage in 2014, have led to an increased demand for more sophisticated and modern medical equipment and supplies. Total imports of medical equipment grew from $584 million in 2010 to $624 million in 2011, with U.S. imports accounting for 20 percent of this market. Continued strong growth for this market is predicted over the next two years. U.S. manufacturers of medical devices should take advantage of this growing market.

Market Entry

U.S. companies must appoint Indonesian agents/distributors to market medical equipment and supplies in Indonesia. Local agents/distributors play an important role in developing the market and providing after-sales services.

Current Market Trends

Indonesians spend over $1 billion annually for quality healthcare overseas, mostly in Singapore, Malaysia, Thailand, and a few other countries. In a bid to stem the flow of patients seeking medical treatment abroad and to stay competitive, both government and private sector hospitals continue to upgrade their facilities. The government will establish and enhance the quality of internationally accredited hospitals in at least five large cities in Indonesia with a target of three cities in 2012 and five cities in 2014; this will spur the growth of the medical equipment market in general. Meanwhile, many public hospitals are participating in ISO programs that improve service quality and generally require the use of more sophisticated equipment. Indonesia has 1,520 hospitals and 8,737 health centers (Puskesmas). These hospitals and health centers provide health services to more than 237 million people spread over the 33 provinces of Indonesia. Central and regional governments continue to upgrade their facilities in order to provide basic healthcare services.

Main Competitors

The market for medical equipment and supplies is highly competitive. The U.S. is the largest exporter of medical equipment to Indonesia accounting for 20 percent. Currently, third country producers of medical equipment competing with the U.S. include Japan, Germany, China, France, and other European countries. Germany and Japan hold firm positions in the market. Chinese products are geared more towards low-end supplies and price-sensitive buyers.

Statistics

Capital:	Jakarta
Population:	237.6 million (est. 2010)
GDP:	USD 834 billion (est. 2011)
Currency:	Rupiah
Language:	Indonesian

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Current Demand

Best Prospects

- Diagnostics and laboratory reagents
- Electro-diagnostic equipment and x-ray units
- Rapid tests for HIV, TB, and other infectious diseases
- Life support equipment such as ventilators, anesthesia and patient monitoring equipment

Barriers

There are no restrictions on imports of medical equipment; however, imports of used equipment are prohibited. Medical equipment is subject to a 0-5 percent import tax and a value-added tax of 10 percent. The Ministry of Health controls the registration of medical equipment in Indonesia. In general, products that are FDA-approved and sold in the U.S. will be approved to enter the market in Indonesia.

Trade Events

Hospital Expo

Jakarta • ***hospital-expo.com***

Available Market Research

- Dental Equipment and Supplies (April 2012)
- Medical Equipment and Supplies (May 2011)

Ireland

Summary

Ireland is ranked as having the 13th most consumer-friendly healthcare system in Europe. The market offers American manufacturers of medical equipment and services an opportunity to take advantage of mutual language, business and cultural links and to use the market as a springboard for Europe.

The country has a dual healthcare system, consisting of both private and public healthcare options. The public healthcare system is regulated by the Irish government's Health Service Executive, providing free public health coverage for 1.4 million people with low incomes and those over the age of 65 with modest incomes. A total of 46% of the population are covered by private health insurance.

Public expenditure on healthcare in 2011 was estimated at $17.6 billion, representing a decrease of 5% on 2010. It is anticipated that the national healthcare budget will overrun by $625 million in 2012 and cuts of up to $1.4 billion are expected over the next four years in line with government cutbacks. Healthcare inflation has registered an 8% increase since 2008 compared to an EU average of 4%.

Eleven of the world's top twelve medical device companies are located in Ireland. It is the second largest exporter of medical products in Europe, second only to Germany. 160 medtech companies export over $5.5 billion of products and equipment annually, 50% of which is exported to the U.S.

A strong relationship is maintained between Irish and American universities and hospitals, such as the University of Pittsburgh Medical Center which in partnership with the Beacon Medical Group, manages the independent Beacon Hospital in Dublin. The Cleveland Clinic also operates in Ireland in partnership with the Royal College of Surgeons to research and sell medical devices throughout Europe.

Market Entry

U.S. medical device products are well regarded in Ireland, with the market being highly receptive to American medical equipment/technologies. Ireland, as a member of the Euro-zone, serves as a natural test market and location from which to begin distribution throughout Europe.

U.S. companies exporting to Ireland should obtain local representation through an agent or distributor, of which there are 100 qualified companies in Ireland. CE marking is a legal requirement in Ireland.

Statistics

Capital:	Dublin
Population:	4.58 million
GDP:	USD 221 billion
Currency:	Euro (€)
Language:	Irish, English

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Irish labeling requirements are similar to those used elsewhere in the EU, except Irish authorities require that the name and the EU address of the manufacturer, distributor or packer also appear on the label.

Ireland applies EU tariffs (customs duties) which are based on the international Harmonized System (HS) of product classification. Duty rates on manufactured goods from the United States generally range from 5-8% and are usually based on the c.i.f. value of the goods at the port of entry.

The standard electricity voltage in the Republic of Ireland is 230V a.c., nominal, at 50Hz, with plugs being of the 3-pin IS411 (BS 1363) type. Any electrical item sold on the Irish market should include a 3-pin plug attached (molded) to the power cord. Exporters selling electrical products in the EU must conform to the WEEE and RoHS directives.

Current Market Trends

The Irish government has an ambitious plan to reform the healthcare system by introducing a Universal Health Insurance Scheme. The government is taking steps to tackle the problems of the dual healthcare system by providing better access to A & E facilities, cutting waiting lists and counteracting hospital budget overruns. The government is in favour of primary care centers and is an advocate of preventative medicine focusing on breast, cervical and colon cancer screening.

Cuts in healthcare expenditure have catapulted cost-efficacy and money-for-value products to center stage. Capital spend has diminished with focus primarily on the equipment replacement market. Opportunities exist for products that save time, resources, and produce cost savings in a very price sensitive market. Public tender opportunities are advertised on the eTenders Public Procurement website, ***etenders.gov.ie***.

The Irish government has also identified the medical technology sector as one of the key drivers of future industrial growth and continues to provide support to the manufacturing and R&D sectors.

Main Competitors

U.S. medical device companies include: 3M, Alcon, Baxter, Biomet, Boston-Scientific, Cook Medical, GE Healthcare, Hospira, Johnson & Johnson, Medtronic, and Stryker. Foreign competitors include: B. Braun Melsungen, Philips, Siemens and Smith & Nephew.

International brands have local sales and marketing operations or utilize an extensive network of Irish agents and distributors. U.S. Commercial Service Dublin facilitates introductions to this agent/distributor network for U.S. companies interested in serving the Irish and wider European marketplace.

Current Demand

Ireland has a population of almost 4.6 million people with 192 hospitals, 90% of which have individual purchasing power. Overall government spend on medical devices and technology of 2.5% is below the EU average of 4.5%. Despite the spending cuts, long term demand is expected to continue to grow, with healthcare spending expected to increase to $50 billion in 2020. Currently 11% of the population is over 65 and as they age, further demand will be placed on healthcare and allow for the emergence of niche markets.

The construction of a new 445-bed Children's Hospital has been delayed but the government is expected to name the location of the hospital in September 2012 with an opening date planned for 2016. Growth in the private healthcare sector has slowed down but plans are underway for a small number of private hospitals/clinics and 14 state-of the-art primary care centers. The development of these new projects will provide opportunities for new product and equipment sales.

Distributors are eager to source new products to help them maintain their businesses in a challenging trading environment. Demand for medical equipment exists particularly across the general medical device, diagnostics, hygiene, living assisted and homecare products, bio-medical, dietary supplement, drugs/pharmaceutical, healthcare IT and veterinary sub-sectors.

Registration Process

The Irish Medicines Board is the regulatory authority for medical equipment and healthcare. Detailed information on Medical devices are regulated by EU Directives that set out compliance requirements and procedures including the General Medical Devices Directive (93/42/EEC), the Active Implantable Medical Devices Directive (90/385/EEC), and the In-Vitro Diagnostic Medical Devices Directive (98/79/EC).

Barriers

There are no real trade barriers. Industry groups however support the development of a national medical device evaluation mechanism to help improve market access. Future cuts in healthcare spending will pose a challenge for American suppliers. U.S. medical device manufacturers should promote the long term cost saving, quality, safety and efficacy benefits of their products and equipment at a time when procurement managers are under pressure to achieve short term savings. U.S. companies partnering with distributors should work together to devise creative strategies to bring new products to the market.

Trade Events

IMSTA Annual Innovation Showcase

October 2012 • Dublin, Ireland • ***imsta.ie***

Showcase of the very latest in medical technologies available from medical supply companies in Ireland.

MEDTEC Ireland 2012

October 10–11, 2012 • Galway, Ireland • ***medtecireland.com***

New manufacturing technologies and techniques, commercial opportunities, and clinical and academic research in the medical devices sector.

eHealth Week 2013

May 13–15, 2013 • Dublin, Ireland • ***worldofhealthit.org***

Industry partners and providers, along with important government and regional decision makers from across Europe, connect and discuss health information technology solutions.

Medica

medica-tradefair.com

Israel

Summary

U.S. medical device companies exported $900 worth of medical equipment to Israel in 2011. In spite of a tight public healthcare budget, Israel's healthcare system is well advanced by OECD standards. Israeli hospitals are modern and the medical community is highly professional and capable of quickly adopt new technologies. In recent years, Israel's healthcare policy makers have been focusing on preventive medicine and created public campaigns for early detection of breast and colon cancer. A set of standard, age-based diagnostic procedures was also introduced to the reimbursement list (also known as the "healthcare basket").

Market Entry

The Israel Ministry of Health (MoH) recognizes the U.S. FDA and CE mark for local registration purposes. The licensing procedure for American-made, FDA-certified medical devices is fairly easily facilitated. U.S. companies that are interested in exporting medical devices into Israel should appoint a local representative to apply for a device registration with the MoH. The MoH recognizes FDA's standards and ECRI nomenclature for licensing purposes, as well as the FDA 510(k), Pre-Market Approval (PMA) or Investigational Device Exemption (IDE).

Current Market Trends

- Israel's healthcare market is among the most advanced in the world.
- New, cost effective, technologies and medicines are quickly adopted.
- The U.S. medical device market share is 25% and steady.
- Israel spends around 8% of total GDP on healthcare services and equipment.
- Israel is a global player in the medical field, with one of the world's most highly educated workforce and dynamic economy.
- Israelis have strong connections to the U.S. and are very receptive to American products.
- By exporting to Israel you will gain a stake in one of the region's most important markets.

Main Competitors

Israel is a sophisticated and mature market. U.S. suppliers face intense European competition. U.S. companies should therefore be ready to compete and support their local distributors through educational presentations and material. Major multinationals and large companies have established direct sales and marketing

Statistics

Capital:	Jerusalem
Population:	8 million
GDP	USD 243 billion (2011)
Currency:	Shekel
Language:	Hebrew

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offices in Israel. Other exporters operate through local distributors. There are hundreds of medical distributors that are well established throughout the country.

Current Demand

Israel's elderly population is growing and its life expectancy is high among OECD countries. Therefore, demand for hospital beds, nursing aids and homecare products is up. The market for medical and surgical dressings grew from $13.6 million in 2006 to $20 million in 2008, registering an almost 50% increase. Wound care continues to be a high priority in preventive care. In addition, a well-developed private sector health care in the areas of dental, eye laser surgery and plastic/aesthetic surgery keep up the demand for advanced medical instruments and appliances. Medical tourism is a growing niche service that helps generate additional income for the healthcare sector and supports market growth. Both private healthcare and medical tourism prompt the need and provide the funds for upgrading existing systems and purchasing new medical equipment.

Best sales prospects include minimally invasive surgical instruments and technology that are integrated with imaging capabilities , cardiology equipment, equipment and supplies for plastic surgery, dental instruments, equipment and technologies for pain management, physiotherapy, ozone & oxygen therapy, OR equipment & cost saving single use products, point of care diagnostic kits and wound management technologies. According to the OECD Health Data 2011 during the past decade, there has been rapid growth in the availability of diagnostic technologies such as computed tomography (CT) scanners and magnetic resonance imaging (MRI) units in most OECD countries.

In Israel, the number of MRIs has increased but less rapidly than in many other countries, to reach 1.9 per million population in 2009. This was well below the OECD average of 12.0. The number of CT scanners in Israel has also increased to 9.4 per million population in 2009, which is also below the OECD average of 22.1.

Barriers

All tariffs on trade between the U.S. and Israel have been eliminated since 1995. Because the Israel Ministry of Health uses the FDA's standards for the purpose of issuing licenses, the licensing procedures for American-made, USFDA approved medical equipment are fairly easily facilitated. Israel is a sophisticated and mature market. U.S. suppliers face intense European competition. U.S. companies should be ready to compete.

Trade Events

Medical Device Design & Manufacturing Industry

October 22, 2012 • Haifa, Israel • ***mddmi.co.il***
Innovative medical devices design & manufacturing.

BioMed Israel

June 10–12, 2013 • Tel Aviv • kenes.com/biomed
Biotechnology and medical innovations.

Medax

March 11–12, 2014 • Tel Aviv, Israel • ***stier-group.com/english/fair_medax.htm***
Covers the entire spectrum of medical devices and services.

Available Market Research

Customized market research and company financial reports.

Italy

Summary

Italy is a mature market for medical equipment, and its high per capita income and sophisticated healthcare system translate into demand for a broad range of cutting-edge medical equipment. The Italian market for medical equipment and supplies is the third largest in Europe following Germany and France with about 742 producers and a 30,000 people workforce. The medical device market (excluding dental and optical devices) was valued at approximately USD 10.7 billion in 2010 with imports accounting for USD 9.1 billion. The Italian government is the primary purchaser of medical equipment. Public hospitals account for over 73 percent of medical device sales, while the remaining 27 percent of sales are made to the private sector. The Italian market for medical equipment is highly dependent on imports. Major suppliers are the United States, Germany, France and Japan. The ageing population together with cost-containment measures can favor the use of innovative medical devices for a more effective healthcare system.

Italian Medical Equipment Market, 2010–2012 (in USD millions)

	2010	2011 (estimated)	2012 (estimated)
Total Market Size	10717	10750	10880
Total Local Production	8,867	8900	8950
Total Exports	7,300	7350	7320
Total Imports	9,163	9200	9250
Imports from the U.S.	1,099	1110	1115

Data from ISTAT and Assobiomedica. Above statistics are unofficial estimates based on reports and statistics from Assobiomedica, Istat, and Eucomed.

Market Entry

The Italian government has implemented various European Union (EU) directives related to medical devices, and U.S. companies must be prepared to comply with Italian and EU legislation.

American companies interested in entering the Italian market should carefully select their potential distributors or agents and should also consider cooperative arrangements or joint venture/licensing agreements with Italian partners.

It is up to the Regional Governments to issue specific regulations governing procurement of medical equipment. Most purchases are made by public tenders open to both domestic and foreign companies. Announcements of tenders on public procurements are monitored by the U.S. Mission to the European Union and are available at ***buyusa.gov/europeanunion***.

Statistics

Capital: Rome
Population: 61 million
GDP: USD 1.77 trillion
Currency: Euro (€)
Language: Italian

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All medical devices marketed in the EU must bear the CE mark to certify conformity with EU legislation. Member States have appointed certification authorities or "notified" bodies to grant these compliance certificates. Award criteria are normally based either on the lowest price or on the most economically advantageous quotations.

Current Market Trends

The Italian domestic medical market (excluding dental and optical medical devices) was estimated at approximately $ 10.7 billion in 2010. Major constraints to the sector development are the healthcare cost-containment measures together with the late payment of public hospitals counting for 75 percent of the medical devices sales. Italy imports primarily from Germany (20 percent), the United States (12 percent) and the Netherlands. Majors subsectors, in which Italy has gained a good position are biomedical instruments and electro medical diagnostics.

In 2010, the investment in research and clinical trials represented about 8 percent of the local production turnover counting for $ 646 million. Highly skilled researchers are employed by universities spin off and start-ups, which represents good partnering and investing opportunities for US companies.

Main Competitors

Foreign companies represent the 8.2 percent of the total number of companies producing medical devices. Industry giants such Siemens, Philips, Hitachi and Toshiba are well present in the market. Several U.S. companies have their subsidiaries in Italy like Johnson & Johnson, Baxter, Boston Scientific, GE Healthcare, Medtronic and St. Jude Medical. Italian companies are small or medium size and they are mainly concentrating in six Regions: Lombardy, Emilia Romagna, Veneto, Lazio, Toscana and Piemonte. The sector is highly innovative and there are about 146 start-ups among which 65% received public financing.

Current Demand

Medical Devices

The best sales potential for U.S. manufactured medical equipment is in the following areas: high frequency medical lasers (for multiple applications), endoscopes and diagnostic imaging equipment non-invasive and micro-surgery devices and equipment, anesthesiology equipment, EKG, stimulators and defibrillators, monitoring equipment, telemedicine equipment and services. The Italian market is receptive to high quality and technologically advanced diagnostics and therapeutic equipment and products. The market for ultrasonic medical devices has seen an annual growth of 3 percent. Opportunities exist for innovative products. Prices are considered to be of primary importance.

E-Health

The European e-Health market has an estimated annual value of around USD 20 billion with an annual growth of 3 percent. Considering that the demand for healthcare products and services will rise significantly in coming years, the information technology applied to the healthcare systems is a key enabler for delivering more effective and efficient health care. The new Italian plan (e-gov 2012) calls for investments of over USD 540 million in the 2009-2012 e-health plan and USD 2.8 billion in the longer term, and it is expected to generate savings of at least USD 42 million per year in healthcare expenditures. The new investment plan is expected to accelerate the use of ICT in the healthcare sector, stimulating the innovation process. The health IT expenditures reached USD 695 million in 2010, while telecommunication expenditures were USD 274 million.

Strategic areas, in which there will be investments over the next 3 years at a 25 percent growth rate are electronic health records, ePrescription, clinical records, and a national network of reservation centers and administrative management. Emerging areas, in which analysts forecast high investments in the future with a 60 percent growth rate, are digital management of pharma, patient relationship support (telemedicine) and hospital innovation.

Registration Process

All medical products and equipment imported into Italy require either notification and/or approval from the Italian Ministry of Health (MOH). All new–to-market medical devices must go through an on-line device registration process with the Italian Ministry of Health to be placed in the Italian market. Information on registration procedures is available on the Ministry of Health's website, ***bit.ly/SFj7OQ***.

Barriers

There are no other significant trade barriers or limitations on imports of U.S. goods. Technical specifications are essentially those established by the EU, which have been incorporated into Italian law. Official technical norms are issued by UNI, the Italian Standards Institute, and electrical norms are from CEI, the Italian Electro technical Standards Institute. Information on EU standards is available from the U.S. Commercial Service Office at the U.S. Mission to the European Union at the following address: 40 Boulevard du Regent, 1000 Brussels, Belgium, tel.: 32 2 5082746; fax: 32 2 5131228.

Trade Events

EXPOSANITA'

Bologna • ***www.senaf.it/Expo-Sanita/en***

Italy's largest and Europe's second largest event dedicated to healthcare, held biennially.

IRM

Torino • ***congresso.sirm.org***

Diagnostic imaging equipment in general. Sponsored by the Italian Radiological Society, held biennially.

Available Market Research

- Medical Device Industry (June 2010)
- Healthcare Services (December 2009)

Japan

Summary

Japan's market for medical devices and materials continues to be one of the world's largest. According to the latest official figures from the Ministry of Health, Labour and Welfare's (MHLW's) Annual Pharmaceutical Production Statistics, the Japanese market for medical devices and materials in 2010 was approximately $26.4 billion (up six percent from 2009 in yen terms). Japan's total imports of U.S. medical devices exceeded $6.1 billion in 2010, a 23 percent market share. The demand for advanced medical technologies is expected to increase due to the Government of Japan's intention of making the pharmaceutical and medical device industries key drivers of Japan's future industrial growth and to attract foreign direct investment in these sectors. Also, demand by the general public for first class medical care is expected to grow as the aging population leads to increased demand overall, and as Japanese consumers realize that they have limited access to advanced medical technologies frequently used by consumers in other advanced nations.

Market Entry

Japan does not levy customs duties on medical devices. However, medical devices are heavily regulated under the Pharmaceutical Affairs Law (PAL). A Japanese company that intends to market a U.S. medical device needs to receive a "license for manufacturing/marketing business" (seizo hanbai gyo kyoka). The company holding this license is called a "Marketing Authorization Holder (MAH)". An MAH must be physically located in Japan. The MAH must obtain marketing approval (hanbai shonin) for each product. A U.S. manufacturer intending to manufacture medical devices in the United States and export them to Japan is required to be accredited by the MHLW as an "Accredited Foreign Manufacturer" in the same way that a Japanese manufacturer is licensed. Typically, an MAH can make an accreditation application on behalf of a U.S. manufacturer. A U.S. manufacturer that lacks a Japanese subsidiary can receive and maintain the shonin approval under its own name. However, the U.S. firm will need to designate an MAH when applying for product approval. This Designated MAH (D-MAH) will have to assume the same responsibilities as an MAH. A D-MAH can be a regulatory consulting company or an importer/distributor that holds an MAH license. When a regulatory consultant is designated as an MAH, a U.S. company will need to have a Japanese distribution partner since a regulatory consulting company will not act as a distributor.

If a U.S. firm has a subsidiary in Japan, that subsidiary can become an MAH and then obtain a marketing approval (*hanbai shonin*) for each product. If a U.S. firm does not have a subsidiary in Japan, the company has three options to consider in order to conduct business in Japan:

Statistics

Capital: Tokyo
Population: 127.8 million
GDP: USD 5.9 trillion
Currency: Yen (¥)
Language: Japanese

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1. The U.S. firm can ask their importer/distributor to obtain the *hanbai shonin* under the name of the importer/distributor. In this case, the importer/distributor will have complete control of the U.S. firm's products when the products are marketed in Japan.
2. The U.S. firm can obtain the *hanbai shonin* under their own name by designating their importer/distributor as a D-MAH.
3. The U.S. firm can obtain the *hanbai shonin* under their own name via a neutral third party (formally known as an "In-Country Caretaker") by designating them as a D-MAH.

Current Market Trends

The market remains heavily dependent on imports, especially sophisticated medical technologies. However, many globally available advanced medical technologies are introduced later in Japan than in Europe and the U.S (device lag) or not introduced at all in Japan (device gap). The Government of Japan (GOJ) has recognized that the device lag and gap prevent timely patient access to innovative and life-saving products, and GOJ has been steadily improving review times and processes. In addition, the medical review process could be further improved as a result of the on-going discussions to revise the Pharmaceutical Affairs Law (PAL) that considers the characteristics of medical devices separately from pharmaceuticals.

Main Competitors

The major product categories comprising Japan's domestic medical device production include: diagnostic imaging equipment; therapeutic and surgical equipment; biophenomena measuring and monitoring systems, home therapeutic equipment, dialyzers, and endoscopes. Japanese medical device companies maintain high market share in those product segments. Top Japanese medical device companies, in terms of sales, include Terumo, NIPRO, Olympus Medical Systems, Toshiba Medical Systems, Hitachi Medico, Nihon Koden, Fukuda Denshi, etc. U.S. medical device companies produce a wide variety of medical devices, but they are especially strong in sophisticated segments of the medical market such as pacemakers, advanced interventional cardiology products, orthopedic implants, laser surgical equipment, and advanced diagnostic imaging equipment. Most major U.S. and foreign medical device firms have either a Japan office or a Japanese partner. In April 2009, Japan based U.S. medical device manufacturers launched a new association called the American Medical Devices and Diagnostics Manufacturers Association (***amdd.jp/en***). The AMDD currently has more than 65 member companies.

Current Demand

Given Japan's aging population, with an increasing number of patients with chronic and life-style diseases, medical devices that alleviate pain, complement lost functions, and improve the quality of life (QOL) should show steady growth in demand. Also, the market for in-home care devices, technologies, and health IT related products is expected to grow as the number of people in out-patient care increases. Other promising growth areas include self care and preventive care medical devices and products due to stronger consumer health concerns.

Registration Process

Japan's medical device classification system is based on the Japanese Medical Device Nomenclature (JMDN) codes which are different to U.S. and European classifications. Review processes for medical devices differ depending on the classification. Medical devices are classified by risk level into four classes (Class 1, Class 2, Class 3 and Class 4). Class 1 (lowest risk) is defined as general medical devices; Class 2 (relatively low risk) is defined as controlled medical devices; Class 3 (relatively high risk) and Class 4 (highest risk) are defined as specifically controlled devices. General medical devices can be marketed by submitting a notification to the Pharmaceutical and Medical Device Agency (PMDA). Controlled medical devices, with established certification standards, can be reviewed by third-party certification bodies.

Controlled medical devices without certification standards and specifically controlled devices must be reviewed by PMDA and approved by MHLW.

Barriers

While the regulatory environment is expected to continue to improve and the market for U.S. medical equipment in Japan remains strong, U.S. firms have been facing challenges with pricing and reimbursement due to the GOJ's efforts to contain overall healthcare costs due to the aging population. The GOJ has implemented pricing policies, such as the Foreign Average Price (FAP) rule, to cut medical device reimbursement rates. The FAP rule adjusts the reimbursement prices of medical devices already on the market to no more than 1.5 times the simple average of the actual sales price in four comparator countries (the U.S., Germany, France, and the UK). In the 2012 reimbursement revision, GOJ changed the Foreign Average Price (FAP) rule by adding Australia to the FAP group of countries for new devices. This may cause further downward adjustments in medical device reimbursement rates and make Japanese reimbursements comparable to rates in lower-cost countries.

Trade Events

International Technical Exhibition of Medical Imaging (ITEM)

April • Yokohama • ***jira-net.or.jp/e***

A comprehensive academic exhibition of the latest medical imaging systems and peripheral devices.

MEDTECH Japan

April • Tokyo • ***canontradeshows.com/expo***

Japan's only trade show for technical and engineering professionals from medical device manufacturing companies seeking new technologies and suppliers.

INTERPHEX Japan

June • Tokyo • ***interphex.jp/en***

Asia's largest pharmaceutical industry event, with 1,400 exhibitors and 63,000 visitors.

International Modern Hospital Show (IMHS)

July • Tokyo • ***www.noma.or.jp/english***

Featuring healthcare products, with 380 exhibitors and 78,000 visitors.

HOSPEX Japan (International Hospital Engineering

November • Tokyo • ***www.jma.or.jp/en***

Hospital facility products, health and medical treatment information systems, and more. 200 exhibitors, 35,000 visitors.

There are a number of technical exhibitions held in conjunction with annual meetings of specialized Japanese medical societies. A list of Japanese medical societies is available at ***www.umin.ac.jp/ac/english.htm***. The organizations' home pages are in Japanese and some require membership for access.

Available Market Research

- POCT (Point-of-Care Testing) Market (2009)
- Medical Technology Market (2009)
- Dental Industry (2010)
- Pharmaceutical Industry (2010)
- Medical Capital Equipment (2011)
- Generics market (2011)

Jordan

Summary

- Medical Tourism is 10% of Jordan's GDP
- Total imports: $74 million
- US imports market share: 30%
- Number of Arab and foreign patients who received treatment in Jordan increased by 10%
- 26,000–50,000 are Libyans in Jordan for healthcare
- Medical Accountability Law
- Used/Refurbished Equipment not prohibited
- Required USFDA, CE mark or Japanese certification

Jordan's health care system is regarded as one of the best in the region. Jordan has become a medical tourism destination in the region by offering relatively high-quality care at comparatively inexpensive rates. The boom in private hospitals is keyed to this growing "medical tourism" trade. Medical tourism generates about two-thirds of all the tourism income to Jordan, as patients often travel with their entire families and/or stay for relatively long periods.

Jordan's health care system uses the latest technologies and has highly educated and well trained doctors. Many Jordanian physicians have received some form of medical training in the U.S., giving U.S. products good exposure. Jordanian doctors are respected throughout the region for their expertise, hence their choices of technology influences buying decision throughout the region. Many doctors in the region are trained in Jordan, and many Jordanian doctors work in neighboring countries. The influence of Jordanian doctors' choices in medical technology can impact buying decisions in other countries where they practice. This raises the incentive for US firms to enter the Jordanian market.

Primary health care sector reforms underway include renovating and adding medical diagnostic devices and therapeutic equipment; improving the quality of health care and hospital services; upgrading hospital infrastructure; developing and implementing health information systems, and medical research.

According to the World Health Organization (WHO), 10% of Jordan's GDP goes toward health care, with the public sector financing over 45% of this total. Jordan spent $350 per capita on health in 2010 (more than twice the regional average). By the end of the year 2008, Jordan had 100 hospitals with a total bed capacity of 11,000, and nearly a third of these facilities are in the private sector.

Jordan has the highest per capita rate of health related expenditures after Saudi Arabia and Lebanon. Through 44 public hospitals and 60 private hospitals, it provides health care services for its citizens and over 250,000 patients

Statistics

Capital:	Amman
Population:	6,500,000 (2011)
GDP:	USD 28.84 billion (2011)
Currency:	Jordanian dinar (JOD)
Language:	Arabic (official)

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from neighboring countries annually. Imports of medical equipment and pharmaceuticals exceeded $370 million in the year 2008 and are expected to grow to US $ 519 million by 2013, representing a compound annual growth rate (CAGR) of 7.01%. . The main drivers for growth include the continuing high volume medicine export activity, generated by Jordan's domestic drug manufacturers. Additionally, the epidemiological profile of Jordan indicates an increasing burden of obesity and diabetes-related disorders, which will drive spending in overall healthcare.

Market Entry

For improving standards, Jordan's 2011 focus of health care policy is greater equity and accountability. The government has taken steps including the implementation of medical responsibility, accreditation, and e-health care regulations. The medical responsibility law, expected to pass in 2012, is intended to protect patients' rights, ensure compliance with clinical guideline, and offer reasonable compensation in cases of malpractice. This should help with garnering international accreditation. 14 Hospitals in Jordan have received national accreditation based on reducing medical errors and preventable harm in the hospital, and six hospitals have received Joint Commission International (JCI).

U.S. companies are encouraged to appoint technically strong agents and distributors to sell their products and technologies in Jordan, and participate in leading trade exhibitions, such as the "Arab Health" in Dubai, to create market and product exposure. The U.S. Commercial Service (CS) offers programs to introduce U.S. products and technologies in Jordan.

Parastatal companies purchase commodities through calls for international tenders. These are announced in the daily press. The U.S. Commercial Service at the U.S. Embassy in Amman reports most of these tenders to the U.S. Department of Commerce. U.S. firms must use a Jordanian agent to purchase tender documents from the issuing public sector entity.

In many cases, a U.S. firm may not be able to provide the wide variety of products required in large tenders. However, a company can offer a bid by forming a consortium. Jordanian buyers prefer a single bid or an entire tender rather than having to piece together bids for each component. Public sector hospitals may request credit in their procurement tenders. While suppliers offering credit will certainly have a better chance of winning bids, sales without credit are sometimes made since other factors such as price, quality, and a delivery schedule may be of greater importance.

Ministry of Health tenders are issued by the General Supplies Department, while the University of Jordan, Royal Medical Services and the Ministry of Defense all release their own tenders. Tenders are published in the Jordan Times and the Middle East Economic Digest.

Current Market Trends

Medical equipment: Demand for medical equipment and services should increase during the next few years with the increase in the number of government and privately owned hospitals; new equipment for hospitals under construction; renovated equipment to replace existing equipment in functioning facilities; upgrading clinics and health care structures; expanding health insurance coverage; and shifting from older conventional methods to modern treatment methods. It should be mentioned that since 1998, the Ministry of Health has prohibited the import of used and refurbished medical devices into the Kingdom.

Medical Tourism

In 2004, the MoH set a plan with public and private sectors to generate an annual $1 billion in medical tourism by the year 2010. Medical Tourism experts at the World Bank have ranked Jordan the leader in the Arab region and the fifth in the world as a medical tourism hub. The medical tourism sector annually generates over $1 billion in revenues, as the number of foreign patients from 84 foreign countries

seeking treatment in the Kingdom in 2008 stands at over 200,100 per year a 10.5% increase over the previous year's total of 190,000, outstripping the (8.8%) increase in general tourism arrivals.

A study commissioned by the PHA for the Ministry of Health said 45,000 Iraqi patients were treated by Jordanian private hospitals in 2007, while Palestinians and Sudanese came second with around 25,000 patients from each country, in addition to 20,000 Yemenis, 19,000 Saudis, 10,000 Syrians, and 10,000 Libyans. In addition, more than 1,800 U.S. citizens, 1,200 UK citizens, and 400 Canadian citizens sought medical treatment in the Kingdom during 2007. (Cost of treatment in Jordan for an American patient, including air travel and accommodation, is only 25% of the cost of receiving treatment in the U.S.

In the meantime, Jordan continues to make efforts, such as marketing campaigns and web promotions, to attract medical tourists from new destinations, including the former Soviet Union and Africa. In February 2009 Jordan held an international medical tourism congress aiming to develop new strategies to improve and expand the capacity of the private health sector while also seeking opportunities for growth from other markets. Regulatory policies are also being implemented to gain international quality accreditation to provide standardized protocols for global patients.

Jordan's current medical tourism sector revenues are estimated to reach USD 650–700 million by the end of 2010 and the country is keen to reach its ambitious target of USD 1 billion by 2012. Jordan is aiming to reach the figure of 300,000 medical tourists in 2015, which would bring revenues of USD 1.5 billion.

E-Health Care

E-health care is another key government program aiming to ensure the accountability of the health care system. The government of Jordan began a pilot project in 2011 to expand to the entire health care system, starting with public hospitals. The e-health initiative system will operate the storage, retrieval and updating of the electronic health records (HER) of patients cared for by all the participating health care facilities in Jordan. Ideally the e-health system will reduce danger of errors during treatment. The system will alert the provider of lab results to dangers of drug interactions and it will remind providers when their patient is due for exams or tests.

The ICT Taskforce was created to help modernize and advance the local health industry, and develop Jordanian companies' capacity and skills in developing advanced products and services in the regional and global healthcare industry. The Healthcare ICT Taskforce contributes to revenue generation and job creation, and also enhances the country's brand as a destination for healthcare services and products. Hospitals, both private and public, will continue to expand, and the demand for new hospitals and medical equipment and pharmaceuticals will continue to grow. The new Queen Rania Pediatric Hospital began operation in February 2010, and in Aqaba a new general military hospital is now under construction to replace the old Princess Haya Hospital.

The MoH plans to continue investing in hospital infrastructure throughout the country, improving the quality of health care and hospital services and developing and implementing health information systems. Primary health care sector reforms will include renovating and adding medical diagnostic devices and therapeutic equipment; improving the quality of health care and hospital services; upgrading hospital infrastructure; and developing and implementing health information systems.

The Jordanian dental services sector is also expected to grow over the coming years. Such growth is mainly triggered by the inclusion of dental services to the universal healthcare scheme provided by the Ministry of Health. These government initiatives have been well received by the people of Jordan as most of them have had limited access to dental services. Private dental service insurance coverage also exists in Jordan. Dental clinics at all public hospitals have experienced a large increase in the number of patients using the national healthcare scheme for dental services for all categories of the society.

Current Demand

There is a need in the next five years for 10 hospitals each with 10,000 beds (focus on Amman, Zarqa, and Irbid).

Best Services Prospects include:

- Consulting in hospital administration, quality control and certification standards
- Training

Given the hospital redesign projects and private clinics investments the following equipment offers excellent sales prospects.:

- Medical equipment
- CT scanners
- MRI equipment
- PET scanners
- Physiological monitoring
- Kidney dialysis equipment
- Reagents for automated laboratories
- Laparoscopy surgery
- Endoscopy
- Cardiology equipment
- Cardiology surgery
- Ophthalmology
- Neurosurgery
- Oncology
- Medical supplies
- Electro medical equipment
- UV/IR apparatus
- Surgical medical equipment
- Radiology and imaging equipment
- Sonography equipment
- Endoscopy equipment and flexible scopes
- Anesthesia and operating theatres
- Laparoscopic surgery
- Hospital/clinical furniture
- Sterilization equipment
- Surgical instruments
- Other medical & equipment instruments
- Other electro-diagnostic apparatus

In addition, there is demand for:

- Clinical laboratory consumables (tubes/glasses)
- Plastic surgery equipment and supplies
- Medical/surgical sterilizers
- X-ray, alpha, beta, gamma ray equipment
- Orthopedic & prosthetic appliances
- Clinical lab/diagnostic equipment
- Organ transplant
- Mental health
- E-health
- Healthcare management systems
- Software modules for specific fields and applications (radiology, imaging, etc.)
- Integrated medical insurance solutions
- Medical devices and equipment
- Customer relations management
- Mobile healthcare applications
- Online medical content providers

Registration Process

The Ministry of Health sets technical rules and specifications applicable to all medical equipment to ensure that all products being sold to Jordanian end users meet the requirements of safety and quality. In Jordan, public sector tenders do not require regulatory review if the product has been authorized for marketing in the US, Europe or Japan. Other specifications are stipulated in the tender terms on a case-by-case basis.

Medical equipment procured by the public sector is tested either by the beneficiary itself (i.e. Ministry of Health, Royal Medical Services, etc.) or the Royal Scientific Society. This testing is not applicable to medical equipment procured by the private sector, which is not subject to any testing procedures.

Trade Events

Arab Health

January 28–31, 2013 • Dubai

Kenya

Summary

Kenya is the most developed economy in Eastern Africa and also the economic, commercial, financial and logistical hub of the entire region. Kenya's population is comprised of a large number of young (almost 70% of the population is under the age of 35) well-educated English-speaking, and multi-lingual professionals, and a strong entrepreneurial tradition. Kenya's healthcare markets are one of the fastest growing on the African continent and are expected to register strong double-digit growth with medical devices at 10-11% annually through 2012-2015, clinical chemistry and diagnostic products at 15-25% annually and pharmaceuticals at 12-15% annually over the same period.

Market Entry

The Kenyan healthcare market relies almost entirely on imports of medical devices, pharmaceuticals (at least 70-80%), dental products, laboratory equipment, healthcare IT, clinical chemistry and diagnostics. Kenya is the key logistical conduit into East Africa and many foreign suppliers operating here do business under their own name to manage penetration into the larger, regional market. Success on the Kenyan market requires that local presence and after-sales support be considered via a local representative, for example an agent or distributor, or a joint venture partner or franchisee.

Current Market Trends

U.S. healthcare suppliers are in an excellent position to increase their market share in Kenya due to U.S. technical competitiveness in assuring quality and reliability of U.S. healthcare products although price is occasionally an issue. Leading private sector hospitals are very active in modernizing their medical equipment inventories, while public sector hospitals are constantly re-equipping with improved budgetary allocations. There are concerted efforts by the Government of Kenya (GoK) to attain universal healthcare for all Kenyans by 2030. Additionally, the passage of a new constitution in August 2010 will establish 47 county governments in 2013, each of which will be responsible for providing health facilities and services. These county governments, managed by a county governor, will receive at least 15 per cent of their annual funding from the central government and it is expected that that a large portion of this funding will be used to re-equip county health facilities.

Main Competitors

Major suppliers of healthcare products include India, China, United States, Germany, Belgium, Switzerland, Belgium, South Africa, Italy and Japan. Leading medical companies that sell product in Kenya include: GlaxoSmithKline, Roche,

Statistics

Capital:	Nairobi
Population:	41 million
GDP:	USD 35.8 billion
Currency:	Shilling
Languages:	English, Swahili

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Sanofi Aventis, Pfizer, AstraZeneca, Philips, Siemens, Novartis, Abbot, GE Medical, Becton Dickinson, Drager, and Welch Allyn among others.

Current Demand

Recently issued government tenders for medical equipment indicate requirements for basic equipment such as anesthetic machines, anesthetic trolleys, hydraulic operating tables, delivery beds, infant incubators, mortuary trolleys, hydraulic operating tables, mercurial sphygmomanometers, and oxygen flow meters among others. Best prospects for electro-medical devices include: CT scanners, ultrasound units, X-ray equipment, mammography units, MRI equipment, angiography, endoscopy, biochemistry, hematology, and immunology systems. Best prospects for clinical chemistry and diagnostics are in serology/hematology, immunochemistry, urinalysis, electrolytes analysis, diabetes testing and cardiac markers while those for pharmaceuticals are in affordable patented and generic drugs used to manage HIV/AIDS and associated opportunistic infections, malaria, cancer, diabetes and hypertension. Used and refurbished medical devices have an open market in Kenya so long as they conform to national standards.

Registration Process

The Pharmacy and Poisons Board (PPB) regulates the practice of pharmacy and the manufacture and trade in pharmaceuticals and medical devices in Kenya.

To register a pharmaceutical product please visit ***pharmacyboardkenya.org/index.php?id=10***.

To register a medical device, please visit ***pharmacyboardkenya.org/index.php?id=13***.

Diagnostic kits and reagents that specifically test for sexually transmitted infections (including HIV/AIDS and hepatitis) are required to be evaluated by the National Public Health Laboratories to ascertain the quality and reliability of these products. Product evaluations typically involve 400 tests at a cost of about $1000.

Barriers

In September 2005, the Kenya Bureau of Standards (KEBS) implemented the Pre-export Verification of Conformity (PVoC) program, a conformity assessment and verification procedure applied to specific "Import Regulated Products" from exporting countries to ensure their compliance with the applicable Kenyan technical regulations and mandatory standards or approved equivalents (international standards and national standards). KEBS requires that all consignments of regulated products entering Kenya must obtain a Certificate of Conformity issued by an appointed PVoC country agent, a mandatory customs clearance document in Kenya; consignments of regulated products arriving at Kenyan Customs Points of Entry without this document will be subject to delays and possibly denial of admission into Kenya.

Available Market Research

For the latest Kenya market research, please visit ***export.gov***.

Republic of Korea

Summary

The Korean medical device market was expected to reach USD 3.7 billion in 2011 (estimated at USD 4.4 billion in 2013). Imports account for about 60% of the total market demand. In 2011, total imports of medical devices were estimated at USD 2.5 billion, with U.S. imports, estimated to be USD 1.085.3 million. The U.S. market share represents 43 percent of the import market share.

Korea Medical Equipment Market, 2009–2011 (in USD millions)

	2009	2010	2011 (estimated)
Total Market Size	3157.4	3375.8	3713.3
Total Local Production	2468.1	2564.4	2820.8
Total Exports	1190.1	1454.4	1599.8
Total Imports	1879.4	2265.8	2492.3
Imports from the U.S.	763.0	943.8	1085.3

Exchange Rate: USD 1= KW 1,120 (2009), 1,156 (2010), 1,156 (2011) • Source: Korea Medical Devices Industry Association)

The importation of medical devices requires the assignment of an importer or representative based in Korea to manage medical device approval and to ensure regulatory compliance. As part of the pre-market approval requirements, the Government of Korea requires testing reports of imported devices for safety and efficacy. In addition to the medical device approvals, companies also negotiate pricing terms with the Korean Health Insurance Review & Assessment Service (HIRA) and the National Health Insurance Corporation (NHIC). Current issues for the medical device industry in Korea include reimbursement pricing, re-evaluation of medical devices, and the healthcare technology assessment system for medical devices.

Market Entry

Medical devices are distributed mainly through local distributors. A local distributor may directly cover the whole country on an exclusive basis or a master distributor may contract with other regional sub-dealers for sales nationwide.

Sales leads for medical devices in Korea are normally created through steady communication with local subsidiaries or between distributors/commission agents and physicians on an individual basis. Local representatives call on physicians frequently and provide information on products to maintain good relationships.

Statistics

Capital: Seoul
Population: 48.6 million (est. 2011)
GDP: USD 1.549 trillion (est. 2011)
Currency: South Korean Won (KRW)
Language: Korean

Contact

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One reliable distributor to cover the country on an exclusive basis is highly recommended for the Korean market since Korea is a geographically small country, and major users for high end medical devices are limited to general hospitals and university hospitals. More than one distributor often confuses clients in terms of representation and prices and diminishes the reliability of the foreign supplier.

Current Market Trends

The top 10 medical devices imported to Korea in 2011:

- Stents
- CT systems
- MRIs
- Orthopedic implants (Knee)
- Soft contact lenses
- Dialyzers
- Accelerator system collimator electron applicators
- Surgical instruments
- Ophthalmic lenses
- Ultrasound imaging systems

Main Competitors

Korea depends on high-end medical devices from the U.S., the EU, and Japan to supply about 60 percent of total market demand. Currently, the United States has largest import market share in Korea, followed by the EU and Japan. Korean manufacturers supply primarily low and to medium technology products and equipment.

Current Demand

Market demand for foreign advanced and innovative medical devices in 2011 was estimated to grow slowly since the Korean economy has not recovered. Factors favoring the use of imported advanced medical equipment and devices are the growing number of elderly in the population and Korean doctors educated in the U.S. and Europe who are accustomed to using advanced medical devices.

Barriers

Pre-market License

All medical devices are required to obtain marketing clearance from the Korea Food & Drug Administration (KFDA) before they are manufactured in or imported into Korea. Currently, medical devices are classified into four categories in Korea depending upon technical attributes and product use. KFDA requires pre-market notification for class I devices and pre-market approval for class II, III, and IV devices. Class III and IV devices must pass the most stringent technical review by a KFDA with authorized labs to prove their safety and effectiveness. Since KFDA issues product licenses only to locally based firms, all foreign suppliers must submit required documentation and receive necessary approvals through their Korean importers, or U.S. supplier's corporation located in Korea.

The lead-time for approval is typically 6 to12 months, including company-working time for preparing applications. Although KFDA indicates its requirements for the approval in relevant regulations, specific detailed requirements could be different according to each product item. Thus,U.S. firms should closely work with their Korean importers to determine KFDA's requirements on a case-by-case basis to obtain approvals.

National Health Insurance Program & Reimbursement pricing

Korea has compulsory National Health Insurance (NHI) system for 48.9 million citizens. The NHI system was introduced in 1977 and covered entire population by 1989. The Korean government administers funds, coverage, coding, payment and pricing.

Tariffs

Tariffs of medical devices in Korea currently average 5.4%, ranging from zero to as high as 8%. Due to the Korea-US Free Trade Agreement (KORUS FTA) implemented on March 15, 2012, approximately 85-90% of imported medical devices in Korea will receive duty-free treatment within one year, and tariffs on the rest will be eliminated over the next 7 years.

Trade Events

Korea International Medical & Hospital Equipment Show (KIMES)

March 21–24, 2013 • Seoul • ***kimes.kr/eng/default.asp***

Korea's largest showcase for medical devices and technologies.

Kuwait

Summary

Guided by the 2010 USD104 billion economic development plans, Kuwait is in the midst of a healthcare-related infrastructure boom and is upgrading health facilities throughout the country. In 2012 the GOK set aside more than three billion dollars, almost 15% of the total budget, for healthcare.

On the medical equipment side, in 2012, the GOK set aside approximately USD 500 million for pharmaceutical, laboratory, and disposable medical products. Approximately USD150 million was budgeted for medical equipment for 2011 and the same amount for 2012.

Opportunities for U.S. companies include a broad range of healthcare oriented products and services including medical equipment, hospital supplies, products and services, and specialized applications. Quality control is now being enforced at an increased level. It is estimated that 15,000 healthcare professionals will be needed in the public sector alone in the coming years.

The healthcare sector is moving toward becoming a regulated market sector through reform initiatives that are being implemented. The privatization initiative involves broadening public-private partnerships and giving the private sector a growing role in the provision of healthcare services. Recently, public healthcare centers began referring patients to private medical care providers for services like IVF treatment and physiotherapy. Such soaring healthcare spending reflects the GOK's priority to improve the quality of life for both citizens and expatriates and to treat more Kuwaiti patients in-country. Error: Reference source not found

Market Entry

The GCC has a 5% flat rate tax on imports. Kuwait corporate income taxes for foreign corporations ranged from 15-55%, but have been changed to a flat 15% as of 2008. To be successful in the Kuwaiti market, most U.S. companies should identify, develop and support a local agent, representative, or account executive to manage the marketing strategy for both company and products. Some companies find having a Kuwait partner rather than an agent a good tactic, to avoid tax bills. Prior success in other GCC countries is helpful but companies rely on local experience and knowledge to conduct their business in these markets. Knowing regulations and the general business framework is a difficult task without the support of a competent local agent or business partner. U.S. companies should seek this type of business relationship and understand that the best representatives are those who are already active in their particular sector with cultivated contacts.

Statistics

Capital:	Kuwait City
Population:	3.4 million
GDP:	USD 138 billion
Currency:	Kuwaiti dinar (KWD)
Language:	Arabic (official); English widely spoken

Contact

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In summary, selecting the appropriate agent who will work for you is the single most important step a U.S. exporter can take in Kuwait. Getting competent local legal counsel to craft an agreement that protects your company from future liability is also a key. The best local partners are those who share both the risk and profit with their American partners.

Main Competitors

The Kuwait market is totally dependent on imports for medical devices; while U.S. suppliers enjoy some advantages, including competitive prices, language, and exchange rate, European suppliers are aggressively gaining market share with their close proximity to the market and perceived better customer support.

Registration Process

Kuwait Ministry of Health has the following requirements:

1. Free Sale Certificate from the concern health authority of origin to be legalized by Kuwait Embassy. This certificate should mention the trade name of the product, its volumes or weight, and it should state the product is allowed to be sold freely in the country of origin.
2. Certificate of composition (exact percentages) signed and sealed by the manufacturer.
3. Certificate of analysis signed and stamped by manufacturer.
4. As well samples of each product to be tested.
5. Should have a Kuwaiti importer

Barriers

The need for a Kuwaiti agent, distributor, or partner tends to add to the cost of selling goods in Kuwait.

Imports to Kuwait require three certified and legal copies of the commercial invoice, three copies of the transport documents and two copies of the certificate of origin. The certificate of origin must describe the place of origin of the goods, the full name of the manufacturing plant or producer and the full name of the freight forwarder. It must also show gross and net weight, the trademark shown in the manifest, value, type of packaging and means of transport. The certificate must be certified by the Chamber of Commerce in the exporter country and most of the time by Kuwait Embassy or any one of the GCC states mission in the absence of a Kuwaiti mission.

Kuwait Customs is strict and most of the Kuwaiti importers/companies know the best ways to get the imported items faster to the country.

Trade Events

No Medical or Healthcare events are scheduled for 2013 and 2014. Most Kuwaiti companies attend Arab Health, which is held in Dubai, UAE and other shows held in Germany and the U.S.

The U.S. Commercial Service in Kuwait leads a 20–25 member delegation to Arab Health every year.

Available Market Research

Customized market research and company financial reports. Contact us for more information.

Mexico

Summary

Mexico is a big market for all types of medical devices. Imports of medical equipment, instruments, disposable and dental products reached US $3.9 billion in 2011.

Imports of U.S. products are duty free if they comply with the NAFTA certificate of origin. U.S. products are appreciated because of their high quality and good prices. U.S. companies should take advantage of geographical proximity to start or increase their presence in Mexico.

Market Entry

All medical equipment and devices can be imported duty free with a NAFTA certificate of origin. Imports are subject to a 16% VAT tax over the invoice value.

About 90% of medical equipment and instruments and about 20% of medical disposable products are imported. Medical products of U.S. origin are very appreciated in Mexico because of their high quality, after sales service, and good price compared to other similar quality products.

U.S. exporters of medical equipment and instruments thus have good sales opportunities in Mexico.

Current Market Trends

Most large public and private hospitals try to have modern and very specialized medical devices. Some medium and small private hospitals with limited budgets buy used or refurbished equipment. Public hospitals by law, cannot buy used or refurbished products. In order to save resources, recently many public and private hospitals are hiring companies that offer "integral surgery services" and provide service "per event", offering all the necessary products required to perform a surgery. In this way, hospitals avoid making large investments in materials, pharmaceuticals, and instruments, and also reduce the costs involved in keeping and controlling inventories, and maintaining instruments for specialized surgeries.

All public institutions ask suppliers to register with their organization. These institutions may award purchases under US$3,100 directly to a selected provider. Purchases over that amount must be done through public tenders.

All private health care facilities select suppliers by requesting price quotations. Their decisions are based on the best equipment at the best price.

Statistics

Capital:	Mexico, D.F.
Population:	118 million (est. 2010)
GDP:	USD 1.2 trillion (2011)
Currency:	Mexican peso (MXN)
Language:	Spanish

Contact

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Main Competitors

Most large international corporations offering medical devices have a presence in Mexico. Medium and small foreign suppliers usually sell through legally appointed distributors.

Current Demand

Imports supply 90% of the Mexican market for medical equipment and instruments, and 20-30% of demand for medical disposables and dental products.

In 2011, total imports in these four groups of products reached $3.9 billion. Of these imports 51.7 %, or 2.02 billion dollars, were of U.S. origin. Main competitors are from Belgium, Brazil, Canada, China, France, Germany, Israel, Italy, Japan, Netherlands, South Korea and UK.

Barriers

All medical and health care products that touch or affect the human body need to be registered with the Mexican Secretariat of Health (SSA) prior to sale or use in Mexico.

Foreign manufactures of medical devices need to have a legally appointed distributor/representative in Mexico responsible for the registration process and for the product(s) in Mexico.

To be imported into Mexico, some medical products need to comply with technical standards or NOMs (Norma Oficial Mexicana). All standards are classified based on the Harmonized System Code (HS).

There are few Mexican standards for medical devices, but various agencies are preparing more standards to be issued in the near future. Updated information on NOMs and other sanitary processes can be found at ***cofepris.gob.mx***.

Trade Events

There are some small medical events in Mexico open to the public. However, the most important events for companies offering technology medical devices are the academic events organized by medical academies and associations. These are focused on very specialized niche sub-sectors.

Available Market Research

- Mexican Health Care System, June 2008.
- Events in the Medical Sector 2009, March 2009.
- Labeling for Medical Devices. February 2010
- Sanitary Registration for Medical Devices 2011, December 2011
- Health IT Market Overview, March 2012

The Netherlands

Summary

Following the introduction of major healthcare reforms in 2006, the Dutch Government has used market mechanisms to increase efficiency, and substantially reduce direct government involvement. It still plays a major role in financing and overseeing the health care system.

Health insurers play a pivotal role—they sell healthcare and pharmaceutical insurance to all residents of the Netherlands and the basic coverage provided is identical. Insurers may not set higher premiums for people with pre-existing conditions. Insurers also play a key role in determining how much healthcare providers can charge for their services.

Currently, $74 billion is spent on the provision of health care annually, which equates to 10.4 percent of GDP. The domestic market in the Netherlands is relatively small. Imports plus local production far exceed domestic consumption requirements. The country, with its unique geographic position, functions as a distribution center, re-exporting an estimated 20 percent of imported medical equipment. Approximately 75 percent of the companies within this sector market their products outside the Netherlands.

Industry estimates put the value of the annual market for medical equipment and supplies at around $5 billion, of which equipment accounts for 75 percent of sales.

There are more than 500 medical technology companies and over 35 specialized research centers involved in the development and manufacturing of medical instruments and systems, disposables, furniture, consumables, textiles, and supplies.

There are approximately one hundred medical trading companies in the Netherlands, including three or four large ones. Philips is a major global player. Dutch medical equipment importers are highly specialized, both in terms of product knowledge, and knowledge of the Dutch health care structure. There is a high level of cooperation and communication among importers and medical specialists, user groups, and technicians responsible for maintaining the equipment.

The safety of prescription drugs is governed by the Medicines Act. Both the Health Care Inspectorate (IGZ) and the National Institute for Public Health and the Environment (RIVM) play a regulatory role. Medical devices are subject to stringent safety requirements. The initial marketing authorization and subsequent regulation of such products rely on a European framework. The EU member states work closely together and exchange much information.

Statistics

Capital:	Amsterdam
Population:	16.7 million
GDP:	USD 713.1 billion (2011)
Currency:	Euro (€)
Language:	Dutch

Contact

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The Inspectorate and the RIVM ensure compliance with the European legislation governing medical devices. The Dutch government will press for improvements to the European procedures governing the admission and monitoring of medical devices to ensure full harmonization throughout the EU. The current system of risk categories will be maintained, whereby a product representing a lower level of risk will be subject to less stringent assessment than one with higher potential risk.

Market Entry

Local representation or market presence is essential. U.S. exporters should appoint a medical wholesaler/distributor to represent their products. The International Partner Search (IPS), as well as our tailored Gold Key Service, is available through the U.S. Department of Commerce's Export Assistance Centers.

U.S. firms should be prepared to meet some additional criteria to ensure product acceptance, recognition and marketability when entering the Dutch market:

- Product information should be in Dutch. At a minimum, catalog inserts should be in Dutch.
- Operation and instruction manuals should be in Dutch to ensure proper usage of equipment.
- Ensure reliable after-sales servicing and product support, or select a distributor capable of doing so.
- Maintain close contact with distributors to stay informed about market developments, trade issues, regulations and laws concerning products.

Authorized Representative for Class I products: The manufacturer must have an EU-based authorized representative. The primary task of the authorized representative is to be the point of contact for the national health authorities of the member states. The arrangement between the authorized representative and the manufacturer is purely administrative and subject to a commercial contract specifying the role of the authorized representative.

Current Market Trends

Trends include: increasing demand for medical services; growing pressure to contain associated costs; an ageing population; shifts from institutional towards out-patient care; a move from curative towards preventative care; and high value placed on innovation and new technologies.

Main Competitors

Manufacturing of medical equipment is characterized by a small number of large companies dominating the domestic market and exporting much of what they manufacture. Dutch manufacturers supply about three percent of the world health care equipment market. Dutch suppliers also do well in specific niche markets, including pacemakers, x-ray equipment and diagnostics. Philips is a major manufacturer of medical equipment in the Netherlands. Major competitors are Toshiba, Siemens, General Electric and Drager. GE is a leading importer of x-ray equipment into the Netherlands. Medtronic Inc. is a major supplier of pacemakers. The German company Drager is a leading supplier of patient monitoring systems.

Current Demand

Suppliers in the medical equipment and supplies market serve approximately 100 general hospitals with 44,000 beds, eight university hospitals with 6,000 beds, 69 psychiatric hospitals with 18,750 beds, 15 rehabilitation hospitals with 825 beds, 3 epilepsy hospitals with 1,200 beds, and 16 outpatient hospitals. In addition, there are over 20,000 medical practices, polyclinics, laboratories, and consumers, accounting for 60 percent of sales. Hospital purchases contribute over 40 percent to the total medical equipment and supplies market, with the eight teaching hospitals accounting for the highest proportional share of these purchases.

Barriers

Firms exporting medical devices to the Netherlands will not encounter any trade barriers or quotas. For customs clearance, a product description is required describing the use, origin and value of the product. All electro-medical equipment in the Netherlands must be suitable for use with 220 Volt, 50 cycle electrical current and should have KEMA or similar (TUV) approval.

There are also no restrictions or barriers on the movement of capital, foreign exchange earnings, or dividends.

Trade Events

ESC Congress 2013 (European Respiratory Society)

August 31–September 4, 2013 • Amsterdam RAI • ***escardio.org***

Available Market Research

ISA Medical Equipment & Supplies 2010

New Zealand

Summary

All New Zealanders have access to a sophisticated, healthcare system. New Zealand's health system is comprised of public, private, and voluntary sectors that coordinate to provide and fund healthcare. More than 80% of healthcare is Government-funded. Due to an aging population, New Zealand's total health expenditure by 2050 is due to rise to 12.5% of GDP. For the 2010/2011 financial year, public expenditure was approximately US$10 billion. (Source: New Zealand Treasury). Both the public and private sectors aim to source the best and most-affordable technologies.

The U.S. is an important and significant healthcare supplier to New Zealand providing approximately 40% of total market demand. U.S. companies specializing in healthcare products have a strong reputation in New Zealand based on performance, cost, and reliability. Opportunities exist for U.S. companies specializing in new innovative technologies that reduce overall patient costs leading to faster patient recovery and reduced rehabilitation costs.

Market Entry

We advise American companies to establish a local sales presence to improve their market position and chances of success in New Zealand. While some businesses will open a subsidiary in New Zealand, for most American exporters this means appointing an agent or distributor. We encourage American firms to research three key determinants: the purchasing practices of their target customers, the competitive climate in the New Zealand market, and the importance of after-sales service.

New Zealand Government tenders are advertised on the Government Electronic Tenders (GETS) system, ***gets.govt.nz***. Subscription to GETS is free.

Current Market Trends

Health targets are currently the basis of New Zealand's key health strategies. This country's health targets focus on chronic diseases (diabetes, heart disease, cancers and obesity), child and youth services, primary healthcare, elderly care, elective services and infrastructure. Health targets are linked with extra Government funding. For example, Government investment in building new elective surgery theaters is beginning to help reduce the rising patient numbers for non-emergency surgical treatments.

New Zealand's aging population increases the demand for facilities such as retirement villages with on-site hospitals.

Statistics

Capital:	Wellington
Population:	4.4 million
GDP:	USD 159 billion
Currency:	New Zealand Dollar (NZD)
Language:	English (official)

Contact

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Main Competitors

U.S. companies can expect to face competition in this market from major global suppliers including other U.S. healthcare suppliers. New Zealanders recognize U.S. brands as reliable, robust but not always price competitive. Australia is New Zealand's nearest neighbor and across all sectors its most important trading partner.

Current Demand

The country's aging population influences public healthcare expenditure plans whilst at the same time the Government is committed to delivering essential healthcare services. Higher living standards are contributing to an increase demand for medical equipment. New Zealanders expect accessibility to advanced equipment to manage chronic diseases (chronic diseases account for around 80% of healthcare use). Value for money is a key procurement-making decision. New, innovative technologies are important to meet this objective.

A third of New Zealand's population is concentrated in the Greater Auckland region. Approximately 80% of the population is urbanized. Specialist services are readily available in the main centers of Auckland, Wellington and Christchurch. Auckland is the leading center for advanced medical care in New Zealand.

Registration Process

New Zealand Medsafe—the New Zealand Medicines and Medical Devices Safety Authority—is a business unit of the Ministry of Health. Medsafe regulates by applying a framework that weighs up risks and benefits of medicines and medical devices, ensures there are therapeutic benefits, and manages the potential risks associated with use of these products. MedSafe manages a Web Assisted Notification of Devices (WAND). If not exempted, firms must notify their medical devices to MedSafe via the WAND system. For imported products, the New Zealand resident sponsor undertakes this process. There is no fee for notifying to WAND or maintaining a notification. For more information, visit ***medsafe.govt.nz***.

Barriers

There are no trade barriers against U.S. products and services.

Trade Events

There are no local trade events in this sector.

Available Market Research

2012 Country Commercial Guide

Nigeria

Summary

Nigeria is a net importer of high-end medical equipment and prescription medicines. For medical equipment, local production is limited to peripheral items such as hospital beds and gurneys. For medicines, limited local capacity exists for over-the-counter drugs especially those for treating common cold, malaria and headache. Across the country, there is a dearth of well-trained, well- equipped and adequately motivated medical professionals. Few hospitals and clinics may be truly classified as world-class. As a result, Nigerian's with sufficient means often seek medical attention in countries with more advanced healthcare systems, including the United States, spending an estimated $900 million per year. Industry experts estimate that over 25,000 Nigerian travelers are medical tourists. While this presents an opportunity to U.S. medical institutions, it presents even greater opportunities to suppliers of mid- to high-end medical equipment looking to expand their international markets. For Nigeria's over 150 million people, there are about 13,703 primary care, 845 secondary care and 59 tertiary care facilities. The private sector is expected to be the primary driver of growth in the health sector as healthcare demand in Africa is projected to double from $17 billion in 2005 to $35 billion in 2016.

Nigeria enjoys strong healthcare professional associations such as the Nigerian Medical Association (NMA) and Pharmaceutical Society of Nigeria (PSN).

Market Entry

The best way for U.S. manufacturers and suppliers to penetrate the Nigerian market is to combine the benefits of the network services and programs of the U.S. Commercial Service with the extensive knowledge, industry contacts and services of CS trade professionals at the U.S. Consulate General in Lagos, Nigeria. We encourage seeking the assistance of a CS trade professional before exploring an opportunity in this market. For establishing a presence in Nigeria, we recommend that U.S. firms use an agent/distributor relationship with a locally registered company. Terms and conditions must be fully defined up front.

Main Competitors

Imports from Europe, particularly Austria, account for over 60 percent of Nigeria's market for medical equipment, and Nigeria imports over 60 percent of medicines for all types of treatment from outside the country. The United States accounts for less than 30 percent of this market both for equipment and drugs. For both new and used equipment, price is the most competitive factor followed by service support and product origin.

Statistics

Capital:	Abuja
Population:	160 million
GDP:	377 billion (est.)
Currency:	Naira (NGN)
Languages:	English (official); Igbo, Yoruba, and Hausa

Contact

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Current Demand

There is high demand for medical services and equipment such as analytical and examination instruments, ultrasound scans, anesthesia equipment, mortuary and laboratory equipment. Top priorities for Nigeria's healthcare agenda include: polio eradication, maternal and child health, malaria control, pandemic influenza prevention and control, and non-communicable disease prevention, among others. Market analysts say malaria is one of the principal causes of illness and death in Nigeria. Current statistics indicate that nine out of ten deaths related to malaria that occur in Sub-Saharan Africa, including Nigeria, are among young children and pregnant women. Tuberculosis is another pandemic in Nigeria, with the country ranking 10th among the 22 high-burden TB countries in the world.

Registration Process

Nigeria has one of the most respected food and drug regulatory agencies in Africa, the National Agency for Food and Drug Administration and Control (NAFDAC). The supervising ministry for national provision of healthcare services is the Federal Ministry of health. The Standard Organization of Nigeria (SON) is responsible for compliance with equipment specification and import standards. SON's Conformity Assessment Program (SONCAP) is designed to educate exporters to Nigeria especially on matters related to product standards and regulations, and to prevent indiscriminate importation of substandard goods into Nigeria. For more information about SONCAP, please visit ***soncap.com*** or ***sononline.org***.

Currently, Nigerian imports are inspected in Nigeria at the port of entry under a Destination Inspection program. CS Nigeria usually recommends that U.S. exporters persuade their Nigerian associates or Nigerian importers of their products to facilitate appropriate import documentations (and issuance of certificates where necessary) with relevant government agencies such as SON and NAFDAC.

Barriers

Unreliable power supply, weak institutions, insecurity of life and property, and collapsing infrastructure.

Trade Events

West African Health International Medical Exhibition & Conference

September • Lagos • ***westafricanhealth.org***

Available Market Research

CCG 2012

Norway

Summary

Norway is one of the wealthiest countries in the world and this is reflected in its expenditure on medical care for its citizens. With the exception of the U.S. and Switzerland, Norway spends more of its GDP (9.8% / USD 42 billion) on healthcare than any other country in the world. The state-dominated medical system, covering 85% of total healthcare costs is striving for technological advances and organizational improvements in a climate of increasing demand and an aging population. By 2020, there will be 40% more senior citizens in Norway than today.

U.S. companies are estimated to supply around 25-30 percent of Norwegian purchases of medical equipment. High end, quality products and a tailored marketing approach are key factors for U.S. companies in penetrating the Norwegian market. The perceived reliability and quality of a product, together with information received from health care providers/relevant certifying bodies/professional associations in Norway constitute the most significant factors in a purchasing decision for Norwegian buyers and end-users of medical equipment.

U.S. medical equipment suppliers have attractive opportunities in Norway.

Market Entry

Finding a local representative with established contacts with the public authorities is the key to success for a new-to-market U.S. company. The availability of technical service also plays an important role. As most communication is through the local language, it is an advantage to have a local representative abreast about of the current market conditions.

Current Market Trends

Demographically, as in other industrialized countries, Norway has an aging population, and this represents an extra burden for the healthcare system. The government of Norway is striving for technological advances and organizational improvements in order to get healthcare costs under control. There is a major health reform underway, named the "Coordination reform" attempting to address the challenges faced in providing healthcare services in Norway. These include the inadequate coordination of services covering patient needs, too few initiatives aimed at limiting and preventing disease, changing demographics/increase in chronic and complex illnesses among the population.

The government has signaled that nursing and care for the aged must be given higher priority, and there is an increasing use of outpatient-based care at hospitals in an effort to rationalize. E-health is also high on the political agenda

Statistics

Capital:	Oslo
Population:	5 million
GDP:	USD 470 billion
Currency:	Norwegian krone (NOK)
Language:	Norwegian

Contact

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Main Competitors

Norway relies heavily on imports of medical equipment. The major third-country suppliers of medical equipment are Germany, Denmark, Switzerland, Sweden, the United Kingdom, and Japan. The Nordic countries (and to some degree Norway's EFTA partner Switzerland) have traditionally had close contact and cooperation in several healthcare related areas over the last decades. Norwegian companies have also had a preference for participating in and seeking trading partners through European, and in particular German, trade events.

Current Demand

Estimates from the public health authorities and trade associations indicate that the total Norwegian market for medical and dental equipment and supplies reached over USD 1 billion by 2011. The various public health care authorities are estimated to account for about 90% of the purchases of medical equipment, whereas private (non-publicly funded) purchases account for the remaining 10%. About half of all medical equipment is sold to hospitals.

High-quality and technically advanced products and a tailored marketing approach are necessary for U.S. companies wishing to penetrate the Norwegian market, in addition to an attractive and functional design. The most promising sub-sectors for U.S. suppliers of medical equipment include surgical instruments and equipment, diagnostic apparatus, orthopedic equipment, monitoring instruments and equipment, laboratory/pathology instruments and equipment, digital x-ray systems and customized ICT equipment. Telemedicine is seen as an important part of future acute medical care.

Barriers

Through the EEA Agreement (European Economic Area), Norway participates fully in the EU internal market and thus in efforts to establish common product requirements and methods of conformity assessment. A CE marking will confirm conformity with the essential requirements of EU/EEA directives, Medical Device Directive (93/42/EEC) and Active Implantable Medical Devices (90/385/EEC). Norway has the same rights and obligations as EU member states in regulation of medical devices. So, all medical products must have pre-marketing approval and bear the CE marking. This marking must be used in order for the product to be placed on the internal EEA market.

There are no other significant barriers to trade.

Trade Events

Lab '14

October 28–30, 2014 • Oslo • ***messe.no***
Trade show featuring laboratory equipment.

Nordental

October 10–12, 2013 • Oslo • ***messe.no***
Trade show featuring dental equipment.

Most Norwegian distributors will attend established international trade shows like Medica in Germany.

Available Market Research

- Clinical Laboratory Market
- Medical Equipment Market
- Rehab and Home Care Market
- Dental Market.

The Philippines

Summary

The medical equipment sector continues to present good opportunities for U.S. firms. Total imports increased by more than 24% from approximately $229 million in 2009 to about $284 million in 2010. The medical industry in the Philippines is almost totally dependent on imports. Additional requirements for medical services, new technology, and equipment replacement spur market growth.

In 2010, the Philippines' total import of medical equipment was $284 million. The U.S. regained its top position, supplying more than 35% of total importation. China 14%, Japan 10%, Singapore 9%, Germany 8%, and Malaysia 6%. About 82% of the Philippines' importation of Medical Equipment came from these 6 countries alone.

Market shares reflect a strong preference for U.S. products. The U.S. performs well with high value, low volume medical equipment such as ultrasound equipment, magnetic resonance imaging (MRI) equipment, breathing equipment, and other radiology and electronic medical equipment. U.S. manufacturers, however, face increasing competition from third country suppliers.

The U.S. dominates the market for durables (machineries and equipment) while China is the top exporter of consumable and disposable medical supplies. Singapore, which ranked fourth in 2010, is the regional base of a number of American and European companies; Import data on Singapore may actually reflect trans-shipments from third country suppliers, including Japan.

Local production consists of parts for medical equipment (presumably microchip parts manufactured in the export processing zones).

The market is price-sensitive, which explains the growing presence of Chinese goods. Hospitals with limited budget source medical equipment from China or Taiwan, and distributors that supply equipment and replacement parts now also carry disposables and consumables.

Market Entry

U.S. suppliers interested in selling in the Philippines should appoint a local distributor. A distributor handles all aspects of importation including registration, obtaining a license, and getting customs clearance for the products. He not only helps facilitate the product's entry into the market, but also assumes responsibility for advertising and promotion through sales and dealer networks. A distributor registers with the Food & Drug Authority (FDA,

Statistics

Capital:	Manila
Population:	103,775,002 (est. 2011)
GDP:	USD 389.8 billion (est. 2011)
Currency:	Philippine peso (PHP)
Languages:	Filipino, English (both official)

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formerly the Bureau of Food and Drugs) before operating and receives a License to Import and a License to Operate (LTO) from the FDA.

The average tariff rate for Medical equipment is 3% plus a 12% value-added tax (VAT). The VAT is based on the valuation determined by the Bureau of Customs for the application of customs duties, plus those duties themselves, excise taxes, and other charges (i.e., charges on imports prior to release from customs custody, demurrage fees, including insurance and commissions).

The Bureau of Customs (BOC) is responsible for customs valuation, classification, and clearance functions.

Current Market Trends

Public hospitals tend to place a greater emphasis on preventive healthcare, while private hospitals concentrate on curative services. Private hospitals have traditionally been equipped with more sophisticated medical equipment due to their larger budgets.

Incidence rates for hypertension and heart diseases, lung and kidney diseases, and other respiratory diseases have remained high. To address the problem, most hospital improvements concentrate on specialized services for radiology, cardiac, lung and kidney examinations, and pathology; thus, demand for ECGs, CT Scans, X-ray and Dialysis machines, and other laboratory instruments should grow.

Dermatology remains a growing specialty as Filipinos are becoming more self-conscious—they now visit dermatological clinics and take advantage of services to improve skin conditions. (For example, acne prevention, whitening/brightening of skin, and anti-aging treatments). The trend may have to do with new-found purchasing power of a large number of young people employed in the outsourcing industry.

Main Competitors

American brands face increasing third-country competition, notably from China, which enjoys 14% market share; Japan, with 10% share; and Singapore with 9%. Industry insiders, however, believe that much of Singapore's share could actually be U.S. equipment that is transshipped through its ports.

With Germany supplying 8% of the market and Malaysia with 6%, approximately 82% of the Philippines' importation of Medical Equipment came from these 6 countries alone.

Current Demand

U.S. influence is very evident in the Philippines and market shares reflect the strong preference for U.S. products. The U.S. is strong in high value, low volume medical equipment such as ultrasound equipment, magnetic resonance imaging (MRI) equipment, breathing equipment, and other radiology and electronic medical equipment.

In the last three years, a large, local holding company called Metro Pacific Investments acquired majority shares of six private hospitals, namely: Makati Medical Center, Asian Hospital, Cardinal Santos Medical Center, Cebu Chong Hua Hospital, Davao Doctors Hospital, and Riverside Medical Center-Bacolod. All facilities were upgraded and outfitted with state-of-the-art equipment and fixtures. All medical products suppliers, including foreign medical equipment companies with Philippine offices and medical equipment distributors representing medical companies, had opportunity to bid for the supply/service of equipment.

Registration Process

Foreign suppliers usually appoint a licensed distributor to represent their interests in the Philippines. Usually, the distributors handle all aspects of importation from registration of the products, to obtaining a license and a clearance. Distributors become responsible for the equipment (capability, safety, market performance, and after-sales service) and, thus, prefer exclusive contracts with foreign suppliers.

The Center for Device Regulation, Radiation Health and Research (CDRRHR) was created to oversee the regulation of medical equipment and devices. While waiting for the new guidelines to be developed and approved, the CDRRHR issues a Certificate of Exemption for all medical devices that are NOT YET required for mandatory registration. The requirements for the Certificate of Exemption are as follows:

1. Letter of intent
2. Brochure of the product with product profile (intended use, etc.)
3. Sample (only when necessary)

Payment for the application of Certificate of Exemption is 500 pesos (approximately US$12.00) per product.

The foreign company must provide complete documentation for its equipment to the distributor who will register them. Complete and correct documentation determines the outcome of registration and the length of registration process.

Barriers

There are no barriers to the sale or purchase of medical equipment of acceptable international standards.

Trade Events

There are no local trade shows dedicated to the medical industry. CS Manila promotes International Buyer Program events such as Clinical Lab Expo, and other healthcare events such as Medica.

Poland

Summary

Poland, the sixth largest country in the European Union with a population of 38 million people, represents one of the biggest health care markets in Central/Eastern Europe. That stated, the health care sector in Poland has been in a somewhat challenging financial condition of late, and the short-term outlook in the public healthcare sector remains tentative. Since 1999, the health care sector has gone through several unsuccessful attempts at reform. It is expected that the current government will prepare and Parliament will pass major amendments to the existing Health Care Law and Regulations. The main concerns are in the areas of restructuring, privatization, transparency in treatment standards, and control of the reimbursement system. The traditional public health care sector (the largest sector of health care in Poland) needs investment and management skills to meet the growing demand from patients and at the same time remain within cost controls. These continuing issues heavily influence the purchase of medical supplies in general. Once these new laws become the legal basis as established legislative reform, U.S. Commercial Service Warsaw foresees significant opportunities for U.S. companies.

American suppliers of medical products have a good reputation for high quality products. However, technological advantage is not the only factor determining success in the Polish market. American companies should focus on educating end-users and other players in the health care sector. Participation in medical events, conferences and seminars is a very effective avenue for promotion in Poland. A successful exporter should strongly support its agent/representative at all external marketing events—in particular, medical specialty seminars and conferences. Introducing new products successfully requires an investment of considerable time and expense.

Market Entry

Marketing strategies in Poland are heavily based on market demand. In Poland, medical specialists recommend products, so a good marketing strategy is to keep doctors well informed about new products. This means that a successful importer will need to have a representative/distributor that promotes awareness of new products, attends medical trade shows, seminars and conferences, and keeps doctors informed by direct campaigns.

Price is a more important factor than quality in Poland's health care market. The second factor is local availability of service and spare parts. Another sale-making factor is quick delivery. U.S. companies are encouraged to identify agents/representatives that can provide the necessary assistance and important and timely information often not readily available through public sources. To

Statistics

Capital:	Warsaw
Population:	38 million
GDP:	USD 514.5 billion (est. 2011)
Currency:	Zloty (PLN)
Language:	Polish

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locate an appropriate agent/distributor, American companies can take advantage of Commercial Service Warsaw's International Partner Search or Gold Key Service.

Current Market Trends

The best prospects for U.S. suppliers are in sophisticated diagnostic equipment, patient-monitoring systems, surgery equipment (high-tech surgical devices and mini invasive surgery equipment), oncology and nuclear medicine, and cardiovascular surgical devices. Advanced diagnostic and operating rooms medical equipment has good market potential, especially equipment that increases efficiency and reduces occupancy rates in hospitals and medical clinics. The idea of implementing controls on health expenditures is not unknown to Poland where the expansion of such alternatives has created a demand for a whole new range of medical equipment that facilitate fewer and shorter hospital stays. The demand for medical equipment and products that will assist new Polish health care controls will continue to increase.

In addition, X-ray equipment currently has great market potential in Poland. According to the Supreme Chamber of Control (NIK) latest inspections, there are 11,000 analogue x-ray apparatus operating in the Polish healthcare facilities that need digitization or replacement with digital equipment. As a result, import of x-ray equipment including parts and accessories represents the highest value of Polish imports of medical devices lately. In 2010, it grew by 7% and was worth almost 312 million PLN.

The need for medical home-care for the increasing elderly population in Poland also brings prospects for the American medical equipment market. The increasing elderly population reinforces the demand for all kinds of equipment and aid-supplies used by nurses and families for home-care. Also, the hygiene sub-sector represents good prospects. Patient and medical personnel safety is of growing concern to both members of the medical profession and the Polish public. Best sales prospects will certainly focus around assuring stringent personnel safety requirements. This is especially due to the concern regarding hepatitis, sepsis and other contagious diseases. In the near future, prevention should receive similar emphasis considering the present focus on protection.

Investment related purchases, such as advanced medical equipment like mammography equipment, EEG equipment, Magnetic Resonance Imaging units, radiography/tomography Units, X-ray equipment, etc., are usually limited to private clinics. Fortunately, this market niche rapidly grew with an average annual growth rate at 20-30% in 2008 (larger private firms grew even faster). However, due to the global economic crisis, the latest annual growth in private medical sector was estimated at only 6-7%.

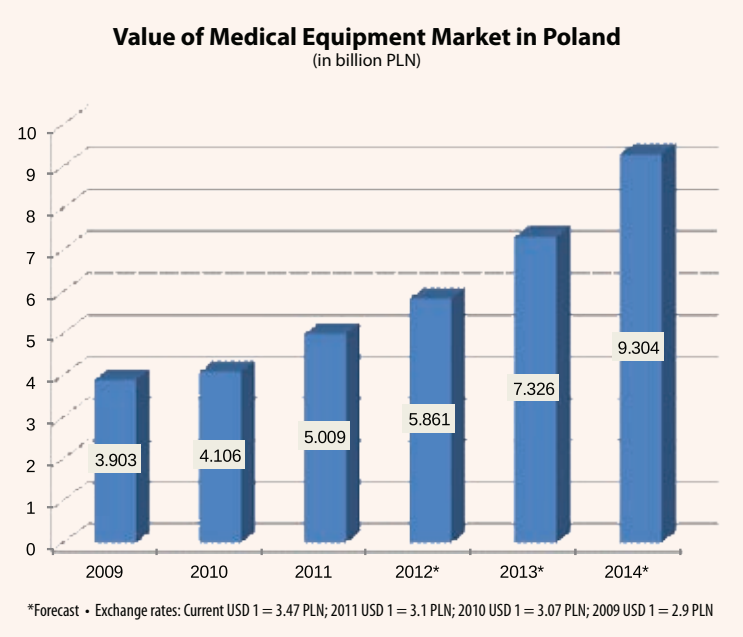
Main Competitors

Polish manufacturers are not very competitive because they lack the latest technology, efficient production methods, investment capital, and appropriate marketing resources. The range of medical equipment produced in Poland is quite limited. Local production is focused on hospital furniture including hospital and rehabilitation beds, lenses, spectacle frames and other ophthalmic devices, and a relatively limited supply of alpha, beta or gamma emission devices, ultraviolet and infrared equipment, dialysis equipment, scintigraphy equipment, and pacemakers.

About 70% of all medical equipment used in Poland is imported. Therefore, medical equipment represents a good prospect for foreign suppliers. However, U.S. medical equipment manufacturers face strong competition from European companies in particular. EU suppliers increased market share due to their competitive prices as well as availability of EU assistance packages for Poland. Poland imports medical equipment primarily from Western Europe (Germany, Netherlands, Austria, France, Switzerland, and United Kingdom), the United States, and Asia (Japan and China).

Current Demand

According to a PMR Research publication on the medical devices market in Poland, in 2010 the medical equipment market grew by 5% over the previous year. By large, it was driven by imports with growth estimated at 6% and 3.9 billion PLN in value. In 2011, the market registered more rapid growth—in the first half of 2011, imports increased by over 30%—which allowed PMR estimating the dynamics of total market growth by more than 20%, with value exceeding 5 billion PLN. Given that, by 2013, the market growth should exceed 25%.



Based on the above statistics, the Polish market for medical equipment will grow quite significantly in the next few years. According to PMR estimates, in 2013–2016 the Polish medical market will grow 25% annually. This growth will be linked directly to the European Union requirement defined in the EU Regulation of February 2011 on sanitary standards and equipment standards required in hospitals and other health care facilities. According to PMR experts, such market growth is feasible in spite of budgetary restrictions and managerial problems within the Polish public health system including the medical equipment reimbursement regulations.

The end-users of medical equipment are the service providers themselves. Service providers include public hospitals, private clinics, and private doctor's offices. One should take into account the difference between the average patient in a private clinic and the average patient of public hospitals and medical facilities. The public sector (the largest sector of health care in Poland) receives annual funding for equipment purchases. Private institutions try to maintain a stock of products based on supply and demand, and generally respond better to a new technology or innovation if it is well marketed.

Barriers

As Poland is a member of the European Union, import regulations for medical equipment are harmonized with the European Union's Medical Device Directives, which cover essential safety, health and environmental requirements. Products manufactured to standards adopted by European standards organizations, and published in the Official Journal as harmonized standards, are presumed to conform to the requirements of EU Directives. The manufacturer then applies the CE Mark and issues a declaration of conformity. With these, the product will be allowed to circulate freely within the European Union.

There are no restrictions in Poland on sales or the importation of used medical equipment by either state-owned or private medical facilities but market opportunities for used medical equipment is relatively small. Medical equipment for the public hospitals is purchased through a competitive bidding process. All tenders are announced in a public procurement bulletin "Biuletyn Zamowien Publicznych" issued by the Public Procurement Office (***uzp.gov.pl/cmsws/page/?F;356***). Private clinics can purchase medical equipment from any sources they wish or through any trading organizations they choose but no specific buying pattern has been identified. Leasing of medical equipment has become more and more popular in Poland, especially among an increasing number of private clinics and private medical facilities.

Trade Events

SALMED

March 2014 • Poznan • ***salmed.pl/en***

The largest event for the healthcare/medical industry sector in Poland. Held biannually.

CEDE

September 12–14, 2013 • Poznan • ***cede.pl/?lang=en***

Central European conference and exhibition for dental industry sector. Held annually.

EXPODENT

October 19–20, 2012 • Torun • ***expo-andre.pl***

National dental conference and trade fair.

REHMED-PLUS EXPO

April 2013 • Kielce • ***targikielce.pl/?k=main_en***

trade fair for rehabilitation, therapy, & spa/wellness medical equipment.

Available Market Research

Additional information on the healthcare-medical sector in Poland as well as more general information on the Polish market, including the country commercial guide, can be requested from the U.S. Commercial Service by visiting ***export.gov/poland/marketresearchonpoland/eg_pl_026434.asp***.

Portugal

Summary

Over 80 percent of medical equipment expenditures are made by the public sector, while 20 percent of sales are made to the private sector in Portugal. The market for medical equipment has improved in recent years and is expected to present increased business opportunities for American exporters in the future. Prices are considered to be of primary importance in all purchasing decisions, both by the public and private sectors.

Market Entry

In order to enter the medical equipment market in Portugal American suppliers should be familiar with the EU directives concerning the registration, marketing, and health/safety standards required throughout Europe as well as regulations specific to Portugal. It is therefore advisable to work with a local partner/ distributor.

Current Market Trends

The Portuguese market for medical equipment is mature and presents a high level of sophistication. Portuguese are educated consumers and expect state-of-the-art medical treatment, which ensures continuous demand for innovative medical equipment and products. One of the prime characteristics of this market is its high level of imports. Total annual expenditures for new equipment are determined in the annual budgets of hospitals. These budgets are prepared according to estimates based on the previous year. The market is very receptive to U.S. products. A considerable portion of the market is penetrated by foreign products and imports from the United States are considered to be very competitive.

Main Competitors

Some of the major US companies with offices and distribution of their products in the Portugal include GE Medical Systems, 3M, and Johnson & Johnson medical. Siemens and Philips also have a strong presence in the country.

Portugal has approximately 300 companies distributing medical products largely comprised of small or medium-sized companies employing on average 15 to 60 people.

Current Demand

High quality and technically sophisticated medical equipment has the best market potential in Portugal, especially equipment that increases efficiency and reduces occupancy rates in hospitals. In Portugal, imports are a fundamental

Statistics

Capital:	Lisbon
Population:	10.6 million
GDP:	USD 237 billion
Currency:	Euro (€)
Language:	Portuguese

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component of the Portuguese medical equipment market. Major suppliers are the United States, Germany, France and Japan. The following products have the best sales potential:

- Surgery equipment
- Patient monitoring systems
- Mini invasive surgery (MIS) equipment
- Video endoscopes
- X-Ray equipment
- Digital image processing
- Magnetic resonance imaging (MRI) equipment
- Picture archiving systems

Barriers

There are no significant barriers on U.S. medical devices or products.

Trade Events

The U.S. Commercial Service Portugal supports U.S. exhibitors at Germany's annual Medica trade show:

Healthcare

November • Düsseldorf, Germany • ***medica-tradefair.com***

Available Market Research

- Medical Equipment Overview 2011
- Over The Counter (OTC) Pharmaceuticals 2011

Romania

Summary

Sales of medical equipment in Romania in 2010 stood at 394 million USD in 2010 (that is around 290 millions Euros), a slightly growing trend as compare to 2009.

The market for medical equipment in Romania increased significantly in the past years as the general level of health spending has increased and new diagnostic equipment was purchased for hospital refurbishments. By 2015, a 9% yearly average growth of the market is expected, accounting for up to around 600 million USD (that is around 440 millions Euros). The medical equipment market will grow in the coming years as a result of growing demand for medical equipment, the development of local producers, the need to meet European quality standards and growing imports.

Market Entry

The segment of consumables is estimated to record 130 million USD in 2015, up by some 44.5% compared to 2010. Analysts estimate that in 5 years consumables will continue to report the biggest sales.

Diagnosis and medical equipment is expected to register 107 million USD in 2015, up by some 41% compare to 2010. The segment of the orthopedic and implantable products is also expected to record 86 million USD by 2015, while the dental products is estimated to register 61 million USD by 2015. Imports cover 86% of the medical equipment market. Romania produces very little in the field of medical equipment, only basic consumables. Despite the fact that locally produced goods are cheaper than imports, they are not as attractive.

Main Competitors

Currently over 100 medical equipment companies are active on the Romanian market with the most important distributors coming from the US, Germany, Italy, France, Japan, China, Turkey and Switzerland. mong them are big names such as GE Healthcare, Roche, Johnson&Johnson, Olympus, Nihon Kohden, Greiner, Becton Dickinson, Beckman Coulter, Bioomerieux, Trinity Biotech and Oxoid. Annual exports of Romanian medical equipment are worth around 30 million dollars, with orthopaedic equipment taking up the lion's share. The countries that receive the most of these exports are Italy, Germany, France, Denmark, and Bulgaria.

Statistics

Capital:	Bucharest
Population:	20.3 million
GDP:	USD 264.269 billion (2011)
Currency:	Romanian leu (RON)
Language:	Romanian

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Current Demand

For 2011, the Ministry of Health invested approx. 190 million USD (approx. 446 million EUR) in order to update the oncology, anaesthesia and intensive care units and to acquire equipment in the medical units subordinated to the Ministry and to the local authorities.

Barriers

For information on existing trade barriers, please see the National Trade Estimate Report on Foreign Trade Barriers, published by USTR and available through the following website: http://www.ustr.gov/about-us/press-office/reports-and-publications/2012

Trade Events

ROMMEDICA

April 2013
Medical equipment and instruments.

ROMPHARMA

Medicines for human and veterinary applications.

ROMOPTIK

Optical equipment and apparatus.

DENTA

November 20–23, 2013
Equipment, instruments, accessories, materials, and chemical/pharmaceutical products for optical equipment and apparatus.

Russia

Summary

The Russian medical equipment and supply market is one of the fastest growing sectors of the economy. There are two factors that explain this high potential growth. First, there is an unsatisfied deferred demand for medical equipment across the country. Second, the Russian government pays close attention to this field, and is making efforts for more transparency and to function more efficiently. These two factors are closely connected because the Russian government decides which medical equipment to buy, this is shaping the demand for more products. In order to support the healthcare sector, a number of government programs were implemented: the reforms of the Mandatory Healthcare System (adoption of the law "About Mandatory Healthcare Insurance" on January 1, 2011), the National Health Project, and the concepts of healthcare development (adoption of the strategic document "Healthcare Through 2020").

Market Entry

- Developing business in Russia is resource intensive, requiring serious commitments of time, personnel and capital.
- Utilize market research and resources, such as with the U.S. Commercial Service's Gold Key or International Partner Search services, to identify opportunities and potential Russian business partners.
- Conduct due diligence, such as with the U.S. Commercial Service's International Company Profile service, to ascertain the reliability of business partners – seek legal consultation and representation.
- Consult with U.S. companies already in the market, as well as with the U.S. Commercial Service and business organizations, such as the American Chamber of Commerce and U.S.-Russia Business Council.
- Communicate regularly with Russian business partners to ensure common understanding of expectations and timelines.
- Frequent travel to Russia is strongly recommended to establish and maintain relationships and rapport with your partners and to understand current and changing market conditions.
- Maintain a long-term timeframe to implement plans and achieve positive results.

Current Market Trends

Recent reforms in the healthcare sector have created opportunities for U.S. medical equipment suppliers. In September 2005, President Putin announced that healthcare would be one of four key national projects, along with education, housing, and agriculture. The total federal budget allocated under

Statistics

Capital:	Moscow
Population:	143 million
GDP:	USD 1.86 trillion
Currency:	Russian ruble
Language:	Russian

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the National Health Project in 2006 was $4 billion (excluding loans and state guarantees) and nearly $5 billion in each of the following years.

The National Health Project is designed to significantly improve the Russian healthcare sector, giving impetus to both the pharmaceutical and medical equipment markets. The implementation of the project is supported by laws and regulations, which will modify the healthcare system structure over the long term. Key laws and regulations include laws on state guarantees for medical assistance, mandatory health insurance, and standards of medical assistance.

In 2010 the National Health Project was financed at $4.8 billion. In 2011 the financing was $3.9 B, in 2012 - $3.8 B, in 2013 – $2.6 B. The significant decline in the figures does not mean that the healthcare spending will decrease, because the numbers mentioned above will be taken only from the federal budget, the rest of the money, intended for providing mandatory healthcare insurance will be drawn from the Mandatory Healthcare Insurance fund. Since contribution payments of all working people to the Mandatory Healthcare Insurance Fund increased by 2%, in 2011-2012 this Fund will receive additional $15.3 billion. In 2010, each region developed its own program of healthcare development.

There are other areas that will receive financial support from the Russian government. The development of Nuclear Medicine will be financed at $4.1 B and the majority of this will be used by the Russian government. The National Oncology program has stated it will receive approximately $1.2 B in invested into their programs. According to " Healthcare through 2020", a document developed by the Ministry of Healthcare and Social Development", Russian citizens will receive high quality medical care, which will be standardized throughout all of Russia. New and more effective medical procedures will be introduced and new medical equipment will be supplied to medical clinics and hospitals. This document is closely connected with the "Concepts of long-term social-economic development of the Russian Federation until 2011", which was adopted in 2008 (revised; 2009). This document states that the expenses for healthcare should be 5.7% of GDP. The medical equipment market should show begin to show growth by the 2013-2016 and reach $15 B by 2020.

The accession into the WTO will also be beneficial for foreign exports to Russia. After full implementation of the WTO accession commitments for tariffs for medical equipment will range from 0 to 7%; currently this figure is as high as 15%.

Main Competitors

According to various sources, imported medical devices constitute almost 60% of the Russian market. The statistical data shows that 40-45% of imports come from Germany, 20-25% from the U.S., 10% from Japan, and 5% each from Italy and France. During the last few years, a growing number of cheaper priced equipment from China and Pakistan have entered the Russian market in large volumes.

Current Demand

Despite recent breakthroughs and the fact that locally made medical equipment is two to four times cheaper than imported equipment, Russian production still lags behind the majority of developed countries. Thus, Russia is still dependent on imports for a significant number of medical equipment, especially those requiring large investments in R&D, innovative technologies, and automation. The best prospects for medical equipment include:

- CTs
- Blood pressure instruments and equipment
- Respirators
- Endoscopes
- Ultrasound scanning equipment
- Syringes, catheters, dental disposables, ophthalmological equipment
- X-ray equipment for general medicine, surgery and veterinary

Barriers

Despite positive changes in the last several years, the medical standards regime in Russia still lacks transparency. Russia continues to rely on product testing as a key element of the product approval process. Other types of product safety assurance, such as plant auditing, quality systems, and post market vigilance are still underdeveloped. Russia continues to follow redundant practices for the testing of internationally accepted certified products, which can delay the entry of products into the country.

Registration Process

All medical equipment manufactured in Russia or abroad need to be registered and certified in order to pass through customs, be sold, and be used in Russia. The following documents are needed.

- **Registration Certificate:** Issued by the Federal Service of Health Care and Social Development Control and is valid indefinitely.
- **ROLE:** Acts as permission for the product to be introduced to the market. Establishes the OKP code (Russian product classification system), in accordance with which the VAT rate is determined for customs clearance of the product—either 0% or 10% (the standard VAT rate is 18%);

IPR in Russia is a very important topic and strong due diligence will need to be a priority for any company wishing to business here.

Before starting the process of registration a manufacturer of medical equipment should keep in mind that the process itself is rather complicated since the regulatory procedures continuously change and are written only in Russian. Thus it is highly recommended that U.S. companies work through their Russian representative, subsidiary, Russian distributor, or a specialized consulting company to navigate the process.

Trade Events

Zdravookhranenie

Moscow • ***zdravo-expo.ru***

International exhibition of medical equipment and drugs.

Saudi Arabia

Summary

The Saudi health care sector is the largest in the Middle East North Africa region. The Saudi Ministry of Health five year strategic plan calls for the construction of five new medical complexes, 190 hospitals, and 1,400 Primary Health Care Centers (PHCCs). In 2012, the health sector was allocated more than $23 billion in the government budget, accounting for 68 percent of total health care expenditures. Total health care expenditures are expected to reach $33.8 billion in 2012.

Market Entry

Although one hundred percent foreign ownership is allowed, it is advisable for U.S. companies to designate a local agent/representative to conduct business in Saudi Arabia. It is also advised that companies work with local legal counsel when drawing up a contractual agreement. Shari'a courts are the courts of general jurisdiction in the Saudi judicial system, and these courts review all foreign court decisions to ensure consistency with Shari'a law.

Medical equipment is charged a 5% customs duty; in some instances, however, imported equipment is exempted, notably if the shipment is bound for a government entity and/or a government project.

The Saudi Food & Drug Authority (SFDA) monitors and controls the import and distribution of medical devices, pharmaceuticals, and food products. For medical devices, the SFDA will usually accept, register, and authorize the marketing and sale of any device that complies with applicable provisions of the SFDA's Interim Regulations and relevant regulatory requirements applicable in one or more of the countries of the Global Harmonization Task Force (GHTF), which includes Australia, Canada, Japan, USA, and EU/EFTA

Current Market Trends

The public sector dominates the supply of health care services in Saudi Arabia and account for the majority of health care expenditures. The public health sector represents 68 percent of total health care spending and approximately 87 percent of bed capacity. With the implementation of a compulsory health insurance system, the private sector's contribution to the Saudi health care

Statistics

Capital:	Riyadh
Population:	27.5 million
GDP:	USD 577 billion
Currency:	Saudi Riyal (SAR)
Language:	Arabic

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system has been growing faster than the government's rate of growth, especially in terms of additional bed capacity and expenditures.

The Saudi pharmaceutical market is highly dependent on imported drugs: 85 percent of the market is accounted for by imports. Pharmaceutical sales are expected to top $4.3 billion in 2012, growing an average of 13 percent annually. Over seventy-four percent of all prescription drugs sold in Saudi Arabia are patented drugs.

Morbidity and mortality statistics reflect that major diseases in Saudi Arabia include diabetes, respiratory infections, and cardiovascular disease. Recent trends also reflect an increasing rate of oncology patients—especially health services to combat breast cancer.

- Over 30% of the population is classified as overweight
- Asthma affects 10-15% of children
- More than 22% of the population are regular smokers
- Growing prevalence of cancer patients, 52.7 per 100,000
- Heart disease increasing an average 5.3% annually
- An estimated 17% of the population is diabetic

Main Competitors

The Saudi market is completely dependent on imports for medical devices; while U.S. suppliers enjoy some advantages, including competitive prices, language, and exchange rate. European suppliers are aggressively gaining market share with their close proximity to the market and perceived better customer support.

On the other hand, the pharmaceuticals sector is characterized by a growing domestic manufacturing base, mainly for generic and OTC drugs, as well as licensing arrangements with branded research-based foreign innovative drug manufacturing firms. The Saudi domestic pharmaceutical industry lacks R&D capabilities, and it remains focused on producing basic formulations of off-patent preparations to feed into the generics market. The lack of R&D is compounded by an unpredictable IPR regulatory system and recently a vague pricing structure which is affecting the introduction of many new research-based products into the market.

Nonetheless, government policies are biased in favor of domestic producers, providing them with exemptions, including interest-free funding, subsidized utility charges, and no import duties on raw materials and intermediate products. Industry sources estimated that domestic production accounts for about 8–9 percent of the total pharmaceutical market, which is approximately USD 365 million.

Current Demand

Total health care expenditures are estimated at $33.8 billion in 2012. The demand for health care services has continuously outgrown supply and both the public and private sectors are struggling to accommodate growing demand. A growing population, compulsory health insurance coverage, and the prevalence of diseases that strike the affluent are serving to boost the demand for services and hospital bed occupancy. The Ministry of Health plans to build 17 hospitals in 2012. Most pressing is the $1.2 billion King Fahd Specialist Hospital in Dammam; while the MOH is completing the construction of 137 hospitals, especially expanding and upgrading the King Faisal Specialist Hospital in Jeddah and the King Fahd Medical City in Riyadh. In March 2011, His Majesty King Abdullah allocated an additional $4.27 billion to the MOH to build and expand:

1. King Fahd Medical City in Riyadh for a tumor center, a heart center, a neurology center and a research center
2. King Abdullah Medical City in Makkah for completing the hospital and centers for heart, organ transplant, tumors, neurology, Ob-Gyn, eye, and rehabilitation

3. King Faisal Medical City in the Southern Province for a hospital, in Abha, an eye hospital, a rehabilitation center, and centers for heart, neurology, and tumors
4. Prince Muhammad Bin Abdul Aziz Bin Abdul Rahman Al Saud Medical City in the Northern Region for an eye hospital, a rehabilitation center, and centers for tumor, heart, and neurology
5. The construction of intensive care centers at medical cities and specialist hospitals across the Kingdom, as well as completion of works at King Khaled Specialist Eye Hospital in Riyadh
6. King Khaled Medical City in the Eastern Province for a hospital in Dammam, an eye hospital in Dhahran, and centers for heart, tumors, rehabilitation, neurology, and research

Other government organizations also have plans to build new hospitals and/or expand existing ones, including:

- The Ministry of Higher Education plans to build 20 teaching hospitals
- The Ministry of Interior plans to build two 1400-bed medical cities/complexes in Riyadh and Jeddah
- Supply of a Hospital Information System for the Medical Services Department at the Royal Commission for Jubail & Yanbu
- The Ministry of Defense & Aviation already awarded the design work for a 3000-bed medical city in Riyadh

Major players in the Saudi health care sector include (by expenditures):

- Ministry of Health
- Saudi Arabian National Guard
- Ministry of Defense & Aviation
- Ministry of Higher Education
- Ministry of Interior
- General Organization for Social Insurance
- Royal Clinics
- Saudi Aramco
- Private Sector
- Executive Board of the Health of the Health Ministers' Council for the GCC States

Registration Process

The Saudi Food & Drug Authority (SFDA) monitors and controls the import and distribution of medical devices, pharmaceuticals, and food products. For medical devices, the SFDA will usually accept, register, and authorize the marketing and sale of any device that complies with applicable provisions of the SFDA's Interim Regulations and relevant regulatory requirements applicable in one or more of the countries of the Global Harmonization Task Force (GHTF), which includes Australia, Canada, Japan, USA, and EU/EFTA. More information on the registration process can be found at ***sfda.gov.sa/en***.

Barriers

Commercial Dispute Settlement

The enforcement of foreign arbitration awards for private sector disputes has yet to be upheld in practice. Each arbitration award or legal decision must be reviewed—in effect, retried—in a local court, a process that can take years. Furthermore, government agencies are not allowed to agree to international arbitration without approval from the Council of Ministers, which is rarely granted.

Business Visas

All visitors to Saudi Arabia must have a Saudi sponsor in order to obtain a business visa to enter Saudi Arabia. On the positive side, in May 2008, the United States and Saudi Arabia signed an agreement to grant reciprocal 5-year, multiple-entry visas for business travelers. This agreement represents a significant step forward in the visa process.

Intellectual Property Protection

Intellectual property protection has steadily increased in the Kingdom. Over the last seven years, Saudi Arabia has comprehensively revised its laws covering intellectual property rights to bring them in line with the WTO agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs). The Saudi Government undertook the revisions as part of Saudi Arabia's accession to the WTO, and promulgated them in coordination with the World Intellectual Property Organization (WIPO). The Saudi Government updated its Trademark Law (2002), Copyright Law (2003), and Patent Law (2004), with the dual goals of TRIPs-compliance and effective deterrence against violators. In 2008 the Violations Review Committee created a website and has populated it with information on current cases. The patent office continues to build its capacity through training, and has streamlined its procedures, hired more staff, and reduced its backlog.

In September 2009, the King approved a mechanism to protect Exclusive Marketing Rights (EMR) for certain pharmaceutical products which lost patent protection when Saudi Arabia transitioned to a new TRIPS-compliant patent law in 2004. The Saudi Ministerial Council in December 2009 approved the Kingdom's accession to both the Intellectual Property Owners Association Patent Cooperation Treaty (PCT) and its Implementing Regulations and the Patent Law Treaty (PLT) adopted by the Diplomatic Conference in Geneva on June 1, 2000. The Council of Ministers issued a resolution on 23/11/1428H (December 3, 2007) approving the Law of Trademarks for GCC countries.

Counterfeiting

Although anti-counterfeiting laws exist, manufacturers of consumer products and automobile spare parts are particularly concerned about the widespread availability of counterfeit products in Saudi Arabia. The Saudi Government remains committed to stopping counterfeit products from entering into the country.

Arab League Boycott

The Gulf Cooperation Council (GCC: Saudi Arabia, Kuwait, Bahrain, Oman, Qatar, and the United Arab Emirates) announced in the fall of 1994 that its members would no longer enforce the secondary and tertiary aspects of the Arab League Boycott. The primary boycott against Israeli companies and products still applies.

Government Procurement

Government contracts on project implementation and procurement strongly favor Saudi and GCC nationals. However, most Saudi defense contracts are negotiated outside these regulations on a case-by-case basis. Saudi Arabia published its revised government procurement procedures in August 2006. Foreign suppliers participating in government procurement are required to establish a training program for Saudi nationals.

Shipping

Saudi Arabia gives preference to national carriers for up to 40% of government-related cargos. Two local companies take full advantage of this situation.

Standards and Labeling

As part of the GCC Customs Union, the six Member States are working toward unifying their standards and conformity assessment systems. However, each Member State continues to apply its own standard or a GCC standard. A new ICCP mandates that a Certificate of Conformity must accompany all consumer goods exported to Saudi Arabia. Labeling and marking requirements are compulsory for any products exported to Saudi Arabia.

Trade Events

MEDEXPO Saudi Arabia

April 6–8, 2013 • Jeddah, Saudi Arabia • ***medexposaudi.com***

Products, technology, and services. Covers the full spectrum of healthcare.

Available Market Research

Country Commercial Guide 2012

Serbia

Summary

The continually growing demand for medical equipment in Serbia, as well as in many developing Balkan states, indicates a strong prospect for companies in this field to conduct beneficial business operations in the broader Balkan region. According to Espicom sources, in 2011, the Serbian market for medical equipment and supplies is estimated to be US$198.6 million, or USD 27 per capita. The market shrank in 2010 and in 2011, but it is expected to resume steady growth of 7.5% between 2012 and 2016, reaching USD 286 million, or USD 40 per capita by 2016. Public expenditure for healthcare is low, amounting to 5.5% of GDP in 2011 and, due to austerity measures, it will continue to decline between 2012 and 2013.

Around 92% of the medical device market is supplied by imports, due in part to the implementation of health reforms that increased the demand for new equipment. The vast majority of the market is supplied by imports from Germany and Italy. U.S. suppliers account for almost 15% of Serbia's imports in this sector. The actual share of U.S. imports is much higher than what is indicated in official statistics, because a large percentage of imported medical equipment is produced by European subsidiaries of U.S. firms and thus is registered as originating in the EU.

Market Entry

Medical devices

According to the Serbian tax regulation, all products, regardless of origin, are subject to a 20 percent value added tax (VAT), except orthotic and prosthetic devices that are surgically implanted in the body, which are subject to a 8 percent VAT.

In accordance with Medical and Medical devices Law, the Medicines and Medical Devices Agency of Serbia (ALIMS—***www.alims.gov.rs/eng***) is in charge of issuing marketing authorizations for medicinal products and medical devices, performing laboratory quality control of medicinal products and medical devices, collecting and processing statistical data on trade, and consumption of medicinal products and medical devices.

Even though Serbia has adopted most of the European regulations, the CE mark has not yet been recognized, so medical products from EU have to pass the marketing authorization process. This procedure is more simplified from the one which products without CE mark have to undergo.

Statistics

Capital:	Belgrade
Population:	7.3 million
GDP*:	USD 40.30 billion (est. 2011)
Currency:	Serbian dinar (RSD)
Language:	Serbian

Contact

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The Serbian market is very receptive to high-quality U.S medical equipment. As Serbian health care is widely considered to be under-financed, foreign companies have a competitive edge if they offer financing. Participation in seminars, medical exhibitions, and scientific meetings can efficiently be used as tools for trade promotion.

Medical products are marketed in Serbia through authorized distributors. Major foreign companies either have their own subsidiaries or operate through local distributors. Most distributors handle several brands of similar equipment or several lines.

Pricing is a key factor in selling a medical products in Serbia, as the market is very price sensitive. When purchasing medical equipment, end-users also look for established companies with reliable after-sales service and customer support.

Current Market Trends

The Medical equipment market in Serbia is highly competitive for its suppliers, due to the concentrated size of the Serbian market and the number of diverse importers. In addition, the structure of the public healthcare sector, and especially the bureaucratic process of the existing tender system, make it imperative for U.S. suppliers to develop and maintain relationships with local partners. Competitive strategies focus mostly on pricing, exchange rates, and payment terms, particularly when dealing with public hospitals.

The Serbian market for equipment is mainly import dependant since imports account for over 90% of the total market. Approximately, 65% of Serbia's imported medical equipment and supplies come from European Union countries. Specifically, the key suppliers of medical equipment are from Germany and Italy, and to a smaller degree from France, Netherlands and Slovenia.

According to Statistical Office of the Republic of Serbia, from January to September 2012, Serbia imported medical equipment and pharmaceutical products worth USD 280.3 million.

Best sales prospects for U.S. medical equipment are expected to be cardiovascular diagnostic equipment, non-invasive surgical devices, anesthesia and intensive care equipment, diagnostic imaging (CTs, MEIs) and radiation therapy equipment, as well as for ultrasound equipment, urology equipment, laboratory and testing equipment, tissue and blood bank related equipment. Also, there are good prospects for products such as: ultra-violet of infra-red apparatus used in medical, surgical, dental, or veterinary sciences, as well as apparatus based on the use of X-rays of alpha, beta or gamma radiations, whether or not of medical, surgical, dental or veterinary uses, needles, catheters, cannulae and the like, used in medical and surgical procedures, medical lasers, endoscopes and laser instruments.

GE Healthcare products are well known in Serbia. In addition, U.S. companies Medtronic and Boston Scientific have established strong positions in the sale of cardiovascular diagnostic equipment, pacemakers, and stents. U.S. Alcon is well represented in the area of ophthalmology.

Main Competitors

The Serbian market is overall receptive to U.S. products. U.S. medical equipment enjoys a solid reputation in terms of quality and sophistication. American companies face stiff competition from West European companies in Serbia. The biggest European competitors are Siemens and Philips. The proximity of the European firms to the Serbian market allows them frequent visits to meet end users, to participate in exhibitions and scientific meetings and to provide prompt after-sales services to buyers.

Current Demand

The Health Ministry in Serbia has embarked on a program of reform in the health care system, in an attempt to modernize it and bring it closer to Western standards. These ongoing and future reforms offer U.S. medical manufacturers opportunities to increase their market share in Serbia.

U.S.-manufactured medical equipment enjoys an excellent reputation in Serbia, due to the United States' reputation for state-of-the-art technology, quality, and reliability. However, medical equipment importers and specialists emphasize the real and perceived lack of technical assistance and service support as one of the main obstacles to further growth of U.S. imports within the market. One should also take into account that the Serbian market for medical equipment is still very price-sensitive, due to limited resources.

Best sales prospects for U.S. medical equipment are expected to be cardiovascular diagnostic equipment, non-invasive surgical devices, anesthesia and intensive care equipment, diagnostic imaging (CTs, MEIs) and radiation therapy equipment, as well as for ultrasound equipment, urology equipment, laboratory and testing equipment, tissue and blood bank related equipment. Also, there are good prospects for products such as: ultra-violet of infra-red apparatus used in medical, surgical, dental, or veterinary sciences, as well as apparatus based on the use of X-rays of alpha, beta or gamma radiations, whether or not of medical, surgical, dental or veterinary uses, needles, catheters, cannulae and the like, used in medical and surgical procedures, medical lasers, endoscopes and laser instruments.

Dental Equipment and Supplies

Serbia has dental practices and dentists that offer high quality dental services with affordable prices, which has resulted in an increase of dental tourism. Serbian dental equipment and supply market is dominated by German, Scandinavian, Italian, and French suppliers; however, there is still market potential for U.S. suppliers of teeth whitening systems, lasers, optical instruments, small equipment for implants and root canal treatment, and orthodontics devices.

Barriers

There are no restrictions on imports, provided the medicines are registered or approved for use in Serbia. The import duties range from 1.5–3 percent. Customs duties are not applied to the imports from the countries from the region that Serbia has signed Free Trade Agreements with. According to Serbian tax regulation, all products regardless of origin are subject to a 20 percent value added tax, which is borne by the final customer (hospital or patient), except orthotic and prosthetic devices and medical devices—products that are surgically implanted in the body—which are subject to a 8 percent value added tax.

Trade Events

International Fair of Medicine

Belgrade, Serbia • ***sajam.co.rs/active/en/home.html***

International exhibition of medical, laboratory, dental, and veterinary equipment and instruments, pharmaceutical and other equipment, and medical services. The accompanying program features up-to-date scientific and expert issues in different fields of medicine, laboratory diagnostics, and dentistry.

Resources

Ministry of health of Serbia: ***zdravlje.gov.rs***

Medicines and Medical devices of Serbia Agency: ***www.alims.gov.rs/eng***

Republic Institute for Health Insurance: ***www.eng.rzzo.rs***

Statistical Office of the Republic of Serbia: ***stat.gov.rs***

Singapore

Summary

Demand for healthcare in Singapore is set to grow as the population increases and ages. The island state's population is likely to increase to 5.5 million by 2020. Demand for state of the art medical technologies is also expected to grow as Singapore strengthens its reputation as the region's healthcare hub and center for healthcare excellence offering first class healthcare delivery systems and facilities to both its resident population and the international patient market.

Singapore serves as a showcase for healthcare delivery and medical technology and is considered the gateway to the regional economies of South East Asia. The three key healthcare strategies Singapore is pursuing are clinical research, improving long-term care and moving towards more sophisticated care.

The national healthcare plan covers almost 100% of the population. This augurs well for the healthcare industry as Singaporeans all have access to medical care.

Market Entry

U.S. companies who are new to the market and interested in exporting to Singapore may consider appointing a local distributor to represent their company's product and services. Given the small market size of the island state, most potential distributors would request exclusive rights to sell the product. They will also likely ask for distribution rights for the regional South East Asia countries as Singapore serves as a gateway into the region. U.S. exporters of medical equipment should evaluate the suitability of the distributor based on the company's contacts in the market, their product range and whether their products complement that of the U.S. firm. As the sales in the local market increases, the U.S. firm can look into setting up an on-going presence in Singapore much like how some large MNCs have set up regional offices in Singapore. This brings the U.S. firm closer to their customers, demonstrates their commitment to the region and allows for prompt and enhanced customer service.

Current Market Trends

Singapore's public hospitals and specialty centers engage in clinical research with the many pharmaceutical, biotechnology and medical technology companies based in Singapore. Singapore's goal is to become Asia's premier healthcare hub via the attraction of foreign patients. There is also an emphasis towards a healthy lifestyle and a focus on preventive care.

Statistics

Capital:	Singapore
Population:	5 million
GDP:	USD 222.7 billion
Currency:	Singapore Dollar (SGD)
Language:	English (business); Mandarin, Malay, Tamil

Contact

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Doctors here are also pushing ethical and professional standards, and it is expected that every major hospital in Singapore will have attained the widely recognized American mark of quality health care. Already, several private and public sector hospitals have been accredited by the Joint Commission International (JCI), the overseas arm of the United States' main hospital accreditation agency.

You can review Singapore's medical devices regulations at ***www.hsa.gov.sg***.

Main Competitors

Major competitors of the U.S. are medical devices from Germany, other European economies, Japan and Australia. Local production by multinational corporations and indigenous Singapore companies is primarily for export or contract manufacturing.

Current Demand

Singapore's healthcare services are comparable to those of other industrialized nations. The plan is to raise health spending to reach US$1.37billion / S $2 billion a year in the next five years. The Singapore government is focused on moving up the value chain by building up services that assist research and healthcare delivery in Singapore and the region. A total of 23 hospitals and six specialty centers, provide a complete spectrum of clinical services from basic health screening to complex quaternary care.

Barriers

There are no barriers to entry as Singapore is an open economy and a firm believer in keeping trade open. There are no custom duties on medical devices. A 7.0% goods and services tax (GST) is imposed on all goods sold and services provided, locally. Imports are subject to GST, but payments are refundable on re-exports.

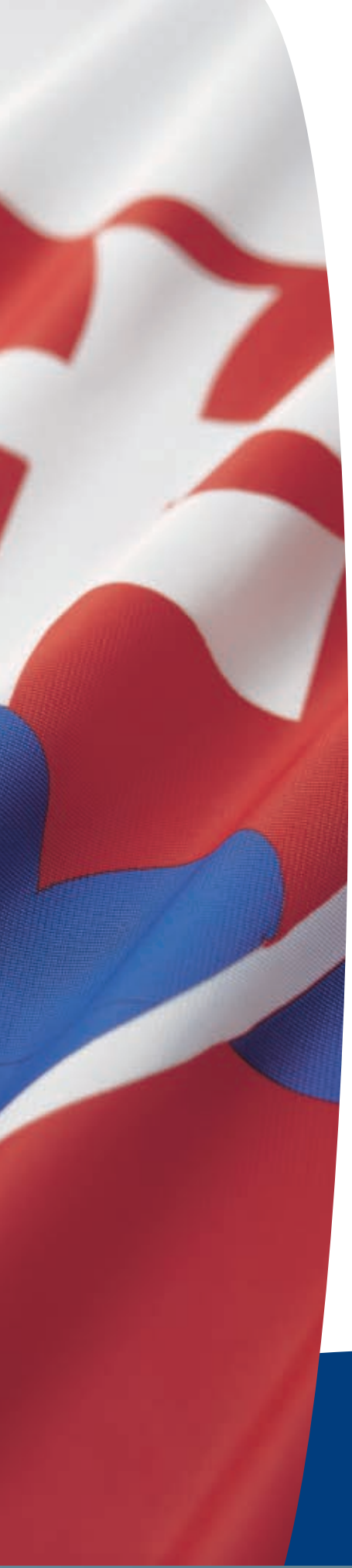
Trade Events

Medical Fair Asia 2014

September 10–12, 2014 • Singapore • ***www.medicalfair-asia.com***
Addresses quality healthcare, upward trend of medical tourism, rising ageing populations, higher life expectancies, and economic development in the Asian markets.

Available Market Research

- Dental Industry 2010
- Healthcare for the Elderly 2009
- Healthcare Overview 2008
- Biomedical Sector Overview 2007



Slovak Republic

Summary

Slovakia's market size is similar to Slovenia and Hungary. Slovakia is seen as complying with international requirements for approvals as well as intellectual property (IP) protection. The country has a tradition of medical device manufacturing, but it is increasingly difficult for domestic production to compete with Western imports. Due to a new government, Slovakia's health care system will be undergoing a profound transformation.

Market Entry

Slovakia is one of the more developed health device and pharmaceutical markets in the Central and Eastern European region. For Slovakia, Euro zone membership has made trade with Slovakia easier by providing more transparent pricing and greater currency stability. A foreign producer that would like to export medical devices into Slovakia must first establish a contract with a local importer, who can help the company fulfill regulations such as the CE mark, Declaration of Conformity, translation of directions and manuals into Slovak, and a guarantee that the product has been approved by the Ministry of Health. Medical devices and pharmaceuticals are also subject to a customs duty and value added tax (VAT) of 20%. Some products carry a 10% VAT.

Current Market Trends

Slovakia continues to implement a new e-Health system, which is part of a project aimed at introducing information technology into healthcare, including e-records and e-prescriptions. The most significant running projects include eSO1 (1st phase of Healthcare Electronization), Unified Reference Database of Healthcare department and Standards and Terminology Care Electronization.

Recently, new legislation was enacted on medicinal products and devices. Changes to conditions of payment for medicinal products, medical devices and dietetic foodstuffs from public health insurance constitutes a major reform of current legislation on medicinal products. Slovakia will no longer have the second cheapest drugs in the EU.

Prime Minister Robert Fico is in rush to acquire private health insurance companies Dovera and Union. Both companies insure about 1/3 of the Slovak population and their estimated market price is EUR650 million ($793 million).

According to 2011 data, the indebtedness of Slovakia's health-care system is EUR150.5 million plus the so-called hidden debt of EUR500 million. This is the sum that hospitals need to invest to improve their effectiveness and in modern technology as well.

Statistics

Capital:	Bratislava
Population:	5.396 million
GDP:	USD 86 billion (2010)
Currency:	Euro (€)
Language:	Slovak

Contact

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Main Competitors

Slovakia's medical device manufacturing sector is skilled, yet it still remains small. Thus, most of the Slovak medical device market is dominated by imports mainly from the U.S. and European Union countries. Germany and the U.S. account for almost 50% of all imports. Local producers focus a large part of their resources on export markets such as the Czech Republic.

284 companies (out of 294) selling pharmaceuticals cover 43.7% of the local market. U.S. pharmaceutical companies, e.g. Abbott, Amgen, J&J, Merck and others, have a 30% market share. According to 2011 turnover, the TOP five pharmaceuticals companies in Slovakia are Sanofi, Novartis, Roche, Pfizer and Glaxo Smith Kline. In 2011 Slovaks spent EUR1.413 billion on pharmaceuticals, out of which 35% were generics.

In Slovakia, there are numerous pharmaceutical distributors, the biggest one being Unipharma. Medications are sold through 2,000 pharmacies. Dr. Max with 178 pharmacies is the biggest pharmacy network.

Current Demand

Slovakia has excellent market opportunities in the fields of sophisticated health technologies and equipment, dental care equipment and many other devices that increase efficiency and reduce occupancy rates in hospitals. The following specific items were the leading exports from the U.S. to Slovakia covered by this "leading sector," ranked by U.S. dollars from January–September 2011:

Leading exports from the U.S. to Slovakia, Jan–Sep 2010–2011 (in USD millions)

Item #	Description	2010	2011
9018	medical; surgical; dental or veterinary instruments	5221902	7846322
9031	machines not specified in chapter 90	4401914	5401403
9030	oscilloscopes; spectrum analyzers	1350621	3201167
9027	instruments for physical anal; microtome	2348982	2987191
9021	orthopedic appliances; hearing aid	2108468	2494827
9026	instruments, measure or check flow; level	1038805	1331755
9024	machines for testing mechanical properties of material	181266	1325121
9032	automatic regulating or control instruments	227237	617406
9015	survey; meteorology	78913	440488
9001	optical fibers & bund; sheets; un-mounted optical elements	194213	335418

Barriers

EUR 650.5 million debt remains a key concern in the Slovak health system.

Medical device or pharmaceuticals importers may sometimes have problems in obtaining approval to be placed on insurance reimbursement lists—something that is also a challenge in other Central and Eastern European countries. If a product is not included on the reimbursement scheme paid by insurance companies, the market for the product is limited. Catalogue of reimbursed operations, medical aids and pharmaceuticals is reevaluated every three months.

Trade Events

SLOVMEDICA

September • Bratislava • ***incheba.sk/vystavy/slovmedica.html?lang=en***

The latest medical techniques, technologies, and equipment for experts active in the field of medicine, workers in hospitals and nursing homes, and experts in health education and science.

NON-HANDICAP

September • Bratislava • ***incheba.sk/vystavy/slovmedica.html?lang=en***

A specialized exhibition featuring equipment and medical aids for the disabled.

SLOVAK DENTAL DAYS

September • Bratislava • ***http://www.incheba.sk/vystavy/slovenske-dentalne-dni.html?lang=en***

Dental instruments, tools, and materials, supported by the Slovak Chamber of Dentists and Association of Dental Producers and Sellers.

Available Market Research

Dental Equipment and Services (2009)

Spain

Summary

According to the Spanish Healthcare Federation, FENIN, the total Spanish healthcare market is estimated to be near Euros 7.7 billion in 2011 (approx. USD 10 billion), down 3 percent over the previous year. Estimates for the 2009-2013 period show an overall average decrease of 2.1 percent.

The sector depends heavily on imports, which represent approximately 80 percent of the total market. U.S. medical equipment and products are highly regarded by Spanish medical professionals and local importers/distributors.

Spain has a comprehensive public healthcare system, spending over 6 percent of GDP on public health expenditures. The public sector accounts for approximately 85 percent of the sector's activity, while the private sector accounts for the remainder.Latest figures available from the OECD show health expenditure (public and private) was 9.6 percent in 2009, up from 8.2 percent in 2005.

While total Spanish healthcare expenditure is in line with the average of OECD countries, Spain ranks below the OECD average in terms of public health spending per capita, with an annual per capita expenditure of USD 3,076 in 2009 versus an average OECD expenditure of USD 3,268. Private expenditure, on the other hand, is in line with that of other major European economies.

Spain is currently struggling with a severe economic crisis. Consequently, as a major recipient of public funding, the austerity measures imposed by the Spanish Government have had a substantial impact on the sector.

Despite relying so heavily on imports, the local industry is gaining ground. Spain has made good progress in the implementation of e-health procedures, and also in neonatal identification coding systems and diagnostics. Spanish exports were reported to be over $2 billion and imports at over $7 billion for 2010. The main export markets are Portugal, the United States, Germany, Belgium, Italy and France. These countries accounted for 65 percent of all export activity. Exports to the United States for 2010 are approximately $270 million. Imports from the U.S. are estimated to be in the range of $1.4 billion, although this figure may be higher as it does not include shipments of U.S. products from other EU markets.

Market Entry

Medical products/equipment imported into Spain need to have the CE Mark. Products and equipment also need to be registered with the Ministry of Health. The importer/distributor frequently works with the U.S. firm on this

Statistics

Capital:	Madrid
Population:	47.2 million
GDP:	USD 1.5 trillion
Currency:	Euro (€)
Language:	Spanish

Contact

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issue. Importers/distributors of medical products also require an authorization issued by the Ministry of Health. As a result of the CE Mark requirement, some U.S. companies have been centralizing their import operations into one single country from which they register and distribute their products to the rest of the EU.

The Spanish NHS -- National Health Service -- is the dominant health care provider and source of procurement. However, each regional community administers its own healthcare budget with the corresponding differences in levels of procurement and reimbursement schedules.

Most purchases (85-90 percent) are made through hospital public tenders from companies that are registered with the Spanish health authorities and pre-selected for the public tender's opening bids. Normally, these pre-selected companies, all registered with the Ministry of Health as authorized importers/distributors of medical products, present their bids and are the ones from whom the hospitals make their purchases. Because of the above procedures, U.S. companies are encouraged to have either a qualified Spanish distributor or their own branch in Spain.

Given the current economic situation, greater emphasis is being placed on cost-effective products and equipment to help reduce healthcare costs.

The import of refurbished medical equipment into Spain is technically permitted, but both public and private medical providers in Spain have traditionally preferred new equipment. Spanish health authorities also require that the refurbished equipment go through the CE Mark process.

Current Market Trends

While the Spanish medical equipment sector has grown over the last several years, current budgetary problems and the growing demand on public health resources is limiting growth. Sector sources indicate a decrease in the volume of activity at 10 percent in 2010, and an estimated additional 3 percent in 2011.

Public health services are administered throughout the country via the corresponding regional governments. The regional governments are the main end-users for medical products and supplies. However, given the economic constraints and cut-backs, procurement has dropped substantially, with orders being reduced to essential basic supplies and equipment. Delays in reimbursement have been a matter of considerable concern. According to FENIN, as of December 2011, the average period for reimbursement by the health authorities had exceeded 470 days for a volume of $7.2 billion (Euros 5.2 billion). The newly elected government has since taken measures to liquidate these outstanding commitments. However, the measures only apply to payments due as of the end of 2011 and, given the current financial situation, it remains to be seen if obligations acquired since then will be paid in a timely manner. A result of the decreased activity in the sector, the overdue payments, and the current crisis, is that many companies are facing severe financial challenges and have difficulty renewing their lines of credit with the banks. Those in a better position are hesitant to take on new products and prefer to take advantage of their contacts and concentrate their efforts on the "basic essentials." Because of the drain on their financial resources, they are also reluctant to take on new products that require investment in market development. As cost efficiency is now a determining factor, depending on the product, the companies are now also more open to Asian products than in the past.

Nonetheless, once this current situation is under control and the economy starts to pick up, demand will also improve. Spending in this sector still has room to catch up with that of other developed economies. Patients are also becoming more knowledgeable about their ailments and treatments available. This eventually will also fuel a demand for more modern and sophisticated equipment. Furthermore, life expectancy continues to improve steadily. This is turn will also generate greater demand for products directly connected with geriatric ailments and illnesses.

Main Competitors

The United States and Germany are the two main suppliers, with France, the U.K., Italy and Switzerland following. However, France, the U.K. and Holland are also used as storage and redistribution centers for U.S. companies. Imports from Asia are on the rise.

Many suppliers in the Spanish industry are subsidiaries of overseas corporations, including leading U.S. firms. These well-established firms often represent serious competition for companies trying to break into the market.

U.S. medical equipment is highly regarded by Spanish doctors, domestic importers, and distributors. However, there has been a significant shift in sourcing in the disposables segment. More and more disposables are being imported from Asia. The explanation given by sector contacts is that the Public Health System, as the principal end-user of imports, is leaning more and more towards cheaper disposable products in an effort to restrain expenditures.

Sweden

Summary

Sweden's health system is one of the best and most well developed in the world. The population of just over 9 million enjoys very good health. Sweden invests about 9 per cent of its GDP in health and medical services, a figure that has been fairly stable since the early 1980s. The infant mortality rate is less than 2.8 deaths per 1,000 in the first year of life and the average life expectancy is 78 years for men and 83 years for women. As Sweden has a population that is one of the oldest in the world, more than 5 percent are 80 years or older, there will be increasing demand for medical equipment and supplies, and longer medical treatments, to meet the health needs of an ageing population.

There are about 33,000 doctors in Sweden, one for every 277 inhabitant. Outpatient care is organized into primary care districts, each with 5,000 to 50,000 inhabitants.

Market Entry

In Sweden three political and administrative bodies control health care for the country: the central government, the county councils and the municipalities. The 21 county councils have the responsibility to provide health and medical services and to work for a good standard of health among the population. The county councils decide on the allocation of the resources to the health services and are responsible for the overall planning of the services offered. It is also the county councils that own and run the hospitals, health centers and other institutions. The 290 municipalities are responsible for the nursing homes, care of the elderly and the disabled. Private health care, accounting for some ten percent of total health care costs, mainly offers primary care like running health care centers or homes for the elderly. There are a few hospitals that are managed by private entrepreneurs.

Sweden's customs laws and regulations follow those of the EU. This means that Sweden applies external EU tariffs to imports from the U.S. and other non-EU countries. Goods imported to Sweden are also subject to a value-added tax (VAT) of 25%. Marking and labeling requirement must follow EU standards, and all instruction manuals must be translated into Swedish.

Sweden uses the metric system. Products sold in Sweden should be adapted for use with the metric system whenever possible. Electric current in Sweden is 50 Hz, AC 230V single-phase and 230/240V three-phase.

U.S. firms interested in entering the Swedish market will find that the market is highly competitive and are therefore recommended to establish a local presence, either through local agents and distributors or sales subsidiaries

Statistics

Capital:	Stockholm
Population:	9.4 million
GDP:	USD 538.2 billion
Currency:	Swedish krona (SEK)
Language:	Swedish

Contact

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Current Market Trends

Two main factors are expected to have strong effects on the future Swedish health care system:

- An aging population, which is likely to lead to increased demand for health care products as well as health care related services such as equipment and supplies for the home health care sector.
- Lifestyle-related diseases and conditions (diabetes, obesity, etc).

Of the predominant diseases and conditions, the main causes of death are cancer and cardiovascular conditions including strokes.

Main Competitors

There are an estimated 480 medical device companies active in Sweden, approximately 180 of which are manufacturing in Sweden. Domestic production is strong and the medical device sector is one of the leading export sectors in Sweden. Some of the internationally known Swedish medical technology companies include Gambro (dialysis equipment, blood component products), Getinge (Medical Systems, Extended Care and Infection Control), Molnlycke Healthcare (single- use surgical and wound care) and Elekta (the Leksell Gamma Knife), Major Swedish dental equipment manufacturers include AstraTech (implants), Nobel Biocare (dental implants), and TePe (oral health products).

Dominating suppliers to the market include the U.S. Germany, Netherlands and Denmark

Current Demand

Although the Swedish health care market continues to operate under cost-containment regulations, there is an eagerness to be at the forefront of technological developments. The market looks to the U.S. for developments in research and application of the newest medical technology. U.S. firms will find that the market is quite receptive to high-quality equipment that offers both ease of use and cost efficiency. Future demand is expected in telemedicine, medical informatics, non-invasive surgical equipment, orthopedic and prosthetic equipment, and Home health care equipment and supplies.

Barriers

Companies exporting to Sweden will not encounter any trade barriers or quotas. Further, there are no restrictions or barriers on the movement of capital, foreign exchange earnings or dividends.

Registration Process

The Medical Products Agency (MPA) is the Swedish national authority responsible for regulation and surveillance of the development, manufacturing and marketing of drugs and other medicinal products. When placing a CE marked in vitro diagnostic device on the Swedish market the following shall be observed: The manufacturer or an authorized representative with a registered place of business in Sweden shall register all products made available on the Swedish market with the competent authority, that is the Medical Products Agency in Sweden.

Trade Events

Apoteksmassan

September 2013, September 2014 • Stockholm • ***apoteksmassan.se***
Pharmacy and over-the-counter products.

Health, Wellness & Fitness

November 2013, November 2014 • Stockholm • ***alltforhalsan.se***

Swedental

November 2013 • Stockholm • ***swedental.org***

Dental trade fair.

Riksstamman

November 2013 • Stockholm • ***riksstamman.se***

Annual general meeting of the Swedish Society of Medicine.

Vitalis

April 2013, April 2014 • Goteborg • ***www.vitalis.nu/en***

Telemedicine and e-health.

Available Market Research

- Telemedicine
- Medical equipment
- Dentistry
- Vitamins

Taiwan

Summary

Taiwan, an island with a population of 23 million, plays an active role in the global economy. In 2011, Taiwan was ranked as the U.S.' tenth largest trading partner in goods. With a vibrant and robust market economy, Taiwan is an attractive market for U.S. goods. The Taiwan economy is characterized by growth, having enjoyed a 4.0% growth in GDP in 2011 and is projected to grow by 2.36%

Taiwan's rising living standards, aging population, longer expectancy and changes in disease patterns have increased the need for health care. Taiwan's public healthcare system, the National Health Insurance program, has been touted worldwide for providing equal access to quality health care for virtually all citizens. The healthcare spending in Taiwan is expected to increase from 7.1% of its GDP in 2010 to 9% in 2015. As a result, domestic demand for medical equipment has remained strong, and over 80 percent of the market is supplied by imports. The U.S. is the leading supplier.

Market Entry

Most new-to-market exporters entering Taiwan begin by finding a local partner to serve as an agent, distributor, and/or representative. Agents are the most common partnerships used by foreign firms to gain their initial foothold in Taiwan. There is a large pool of prospective trade partners that can capably represent U.S. companies in Taiwan. Foreign companies only seeking a distributor in the local market may find difficulty in searching for a partner, as local agencies will perceive these companies as not being serious about the market, and more importantly, may not support these distributors. It is recommended that U.S. firms find a partner willing and able to do some manufacturing, assembly, or customer service in Taiwan, as it signals a US company's deeper commitment to the market.

Current Market Trends

According to the CIA Factbook, those 65 years and older in Taiwan account for 10.9% of the population. The Council of Economic Planning and Development estimates that this number will reach 22.5% by 2028, making Taiwan a "super-aged" society as defined by the United Nations. As such, the demand for quality elderly care and treatment for cancer, cardiovascular diseases, and diabetes will grow accordingly.

The National Health Insurance Program has been troubled by budget deficits, causing stricter rules and regulations on procurement of medical devices and instruments, thus decreasing overall profit margins on medical device sales.

Statistics

Capital:	Taipei
Population:	23 million
GDP:	USD 887.3 billion
Currency:	New Taiwan Dollar (NTD)
Language:	Mandarin Chinese

Contact

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Hospitals in Taiwan are generally modern and well-equipped and as they have to gain the Department of Health accreditation to qualify for health insurance reimbursement, purchasing budgets are increasingly tight. Private hospitals tend to deal on a one-to-one basis with local agents, whereas public hospitals often procure equipment via public tendering handled through the Central Trust of China.

Main Competitors

Taiwan relies heavily on imports for medical equipment and devices. Germany, Japan, and the US dominate the market of imported medical instruments to Taiwan. The U.S. remains the largest medical devices supplier to Taiwan, accounting for one third of total imports, with Germany, and Japan accounting for 14% and 18%, respectively. Domestic production of medical devices consists of low-technology medical devices, totaling 2.3 billion USD in 2011 and a projected value of 2.4 billion USD in 2012.

Current Demand

Best Prospects:

- Cardiovascular equipment
- Endoscopy
- Enclosseous implants
- Computerized tomography
- Ultrasonic scanning apparatus
- Magnetic Resonance Imaging apparatus
- Radiation isotope diagnostic/therapeutic apparatus
- Hemodialysis apparatus
- Chromatographs and electrophoresis instruments
- Shock wave lithotripsy apparatus with X-ray orientor
- X-ray apparatus for dental uses
- Catheters and cannulae
- Artificial joints
- Hip prosthesis, plates, bone screws, and bone cement
- Prepared diagnostic/ laboratory reagents

Registration Process

The Department of Health (DOH) is the local healthcare authority that regulates importation of medical devices. Under the Pharmaceutical Affairs Law, all medical devices are required to obtain pre-market registration approval from the DOH before they can be imported to Taiwan. Since the DOH issues licenses only to locally registered companies, all foreign suppliers must submit required documentation and receive necessary approvals through their Taiwan importers or their Taiwan-registered subsidiaries. Moreover, importers must obtain DOH's pre-market registration approval in order to receive an import license from the Board of Foreign Trade, Ministry of Economic Affairs. As with the U.S. FDA, the DOH has categorized medical devices into Class I, II, & III, depending on the level of risk. In some cases, importers will need to submit a written request to the DOH to determine whether a certain product is a medical device, to which classification it belongs, or if a new classification must be created.

Barriers

Nominal tariff rates are applied ad valorem to the majority of dental and medical devices, mostly ranging from 2.5 to 5%. Foreign firms are typically more concerned with non-tariff barriers, such as regulations. One current issue is differing regulation of medical devices from global practices. Bureaucratic hurdles delay product registration for Class II medical devices, which require both U.S. and EU market clearance documents. These delays hamper growth and the potential to conduct business in the local market.

Trade Events

Taiwan International Medical & Healthcare Exhibition

June 20–23, 2013 • Taipei, Taiwan • ***www.medicaretaiwan.com/en_US***

Medical equipment and services, including hospital equipment, electromedical equipment, emergency medicine and rescue equipment, medical commodities, IT & communication products for medical use, diagnostic instruments and equipment, surgery equipment, pharmaceuticals, and apparatus for dental treatment.

Available Market Research

- Regulatory Environment for Medical Devices (2008)
- Dental Industry (2008)
- Personal Care Products (2010)
- Natural Products Market Update (2011)

Turkey

Summary

Turkey has a population of almost 80 million people and is a growing market for the medical technology products and healthcare services sector. The Ministry of Health (MOH) is the largest provider of healthcare and the only public provider of preventive services in Turkey, to which approximately $8billion was allocated in FY 2012 by the Government of Turkey. A key driver behind Turkey's continued healthcare budget growth is the country's enhanced health insurance coverage and the need to build new healthcare facilities all around the country. Besides investments by the state, the private sector is very involved in building private healthcare facilities which contributes to the purchase of state of the art medical equipment and devices.

Market Entry

U.S. medical equipment manufacturers can either open their own offices in Turkey and equip it with their own sales and marketing force or appoint national, usually exclusive, distributors in Turkey. The distributor/importer should have a strong reseller base to market and service the products all around the country, follow the tenders and also be knowledgeable about shipping products into Turkey. In the latter case, as the distributor/importer will almost be the sole representative of the U.S. manufacturer on the ground, its performance is a very critical factor in the U.S.company's success in Turkey.

Current Market Trends

As the Ministry of Health is the largest supplier of healthcare solutions to the general public, they are pursuing a number of Public Private Partnership (PPP) projects with Turkish and foreign companies to establish healthcare campuses, large medical complexes with several hospitals, labs and recreational areas in large cities. Besides these PPP projects, the Ministry is also renovating the hospitals already operating by upgrading their facilities and technology used. On the other hand, there is a strong trend in the Turkish private sector for investing and building state of the art private healthcare facilities. Especially in the last 10 years, about ten major hospital investors and operators have emerged in the market that are building hospitals all around the country and recently in neighboring countries as well. Construction of many private hospitals offers increased sales opportunities and less complicated procurement requirements compared to the confusing tender requirements used by government agencies. These projects are business opportunities for U.S. medical companies, healthcare operators and service providers.

Statistics

Capital:	Ankara
Population:	79,749,461 (est. 2012)
GDP:	USD 1.087 trillion (est. 2011)
Currency:	Turkish lira (TRY)
Language:	Turkish

Contact

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Medical tourism is a new sector developing in Turkey which is a triggering factor in the investments made by the private sector in healthcare. Increasingly, patients from Europe and the Middle East go to Turkey for medical treatment as costs are more affordable. The size of the medical tourism market in Turkey is around $ 500 million. Increased emphasis on medical tourism will also have a positive impact on U.S. manufacturers as it will bring create avenues for medical equipment exports.

The Ministry of Health has recently introduced a structured primary healthcare system nationwide which assigns a family practioner per 3,000 people. The health situation of each person registered under this system is followed through a comprehensive e-health system. U.S. companies with e-health solutions may find good opportunities for business development in Turkey.

Main Competitors

Imports of U.S. origin represent about 15% of the total imports market in Turkey. The rest are mainly from the European Union, predominantly from Germany, Italy, United Kingdom, France and the Netherlands, and China and India. There is also an emerging group of medical device and equipment manufacturers in Turkey which are active in the manufacturing of disposables, orthopedic devices and tools, surgical and cardiological tools; like stents.

Current Demand

According to figures collected from the World Trade Atlas and industry feedback, these are the estimates of the size of the medical technologies market in millions of US$:

Turkey Medical Technologies Market, 2010–2013 (in USD millions)

	2010	2011	2012 (estimated)	2013 (estimated)
Total Market Size	1911	2094	2270	2490
Total Local Production	210	230	260	300
Total Exports	189	210	230	260
Total Imports	1890	2074	2240	2450
Imports from the U.S.	284	311	336	368

As the healthcare market is in a growing trend and is expected to stay so in the coming years and medical facilities are being built both by state and the private sector, there will be a market for high-end medical technologies and equipment in all areas of medicine, but especially in diagnostics, laboratory systems, and robotic surgery equipment. As there is price-based competition in commodity medical devices and disposables, opportunities could only exist for U.S. companies who can meet these prices.

Barriers

As Turkey is an accession country to the European Union (EU) and has been part of the Customs Union with the EU since early '90s, medical rules and regulations applicable in the EU are mostly applicable in Turkey too. This cannot be considered a barrier but U.S. companies must abide with the requirements set by the EU when selling to Turkey. This implies that FDA certification is in itself insufficient for exporting to Turkey where a CE Mark is required. Due to the Customs Union, products manufactured in the EU are exempt from the customs tax; however the customs tax is levied on some medical equipment and devices imported from non-EU countries which includes the U.S.

Trade Events

MEDIST 2013

November 10–13, 2013 • Istanbul, Turkey
Medical equipment and devices, laboratory equipment, disposables, hospital furniture manufacturers, and healthcare information technology.

EXPOMED 2013 & LAB-TECH EURASIA 2013

April 4–7, 2013 • Istanbul, Turkey • ***expomedistanbul.com*** • ***labtechistanbul.com***
Medical and laboratory technology.

Available Market Research

Available at ***export.gov/turkey/marketresearchonturkey***.

Ukraine

Summary

In 2011, the Ukrainian market for medical equipment and supplies was estimated at $686 million, or $15 per capita, the lowest in Europe. Healthcare expenditures are very low, approximately 6.4% of GDP, which is one of the lowest in Europe. Healthcare funding in Ukraine is largely generated through taxation. Ambulatory and hospital healthcare services are provided predominately by the public sector. According to the Ukrainian Constitution, healthcare should be free for the entire population, but due to a lack of funding, patients are usually forced to make out-of-pocket payments to assure they receive adequate care. A system of public healthcare insurance has been under discussion since 1996. The GOU has announced plans to introduce legislation in 2012 to create a healthcare insurance program by 2015–2016.

Approximately 60% of the medical equipment market is met by imports from the USA, Germany, Japan and China. Ukraine does have some production capacity, but local firms are generally under-capitalized and unable to compete with low priced, quality imports.

The medical equipment currently used in public hospitals is typically obsolete and worn-out. Given the financial condition of many public health institutions, replacement will continue to be slow. Consequently, the number of private clinics and practitioners is growing steadily.

The Ukrainian market is open to advanced medical equipment, offering ease of use and cost savings. Receptivity to used medical equipment is average—on the one hand, there is a demand from end-users, but on the other hand, used equipment cannot be purchased through government tenders. However, private hospitals and clinics are in the market for used medical equipment.

Market Entry

U.S. companies entering the Ukrainian market should approach with a long-term perspective. Business in Ukraine is often based on relationships, so selecting a good local partner and/or establishing a local office are crucial to long-term success. To find a potential partner, we recommend using the U.S. Commercial Service's International Partner Search and Gold Key programs to conduct initial screening for prospective partners. (For more information, please visit ***buyusa.gov/ukraine***.) U.S. companies should use appropriate due diligence in selection of partners and should be mindful of the parameters of the Foreign Corrupt Practices Act.

Statistics

Capital:	Kyiv
Population:	45.1 million
GDP:	USD 305.2 billion
Currency:	Hryvnia (UAH)
Languages:	Ukrainian, Russian

Contact

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Kyiv is not the only trade hub in Ukraine. Look for distributors that have nationwide capabilities, including those located in the cities of Dnipropetrovsk, Donetsk, Lviv, Odessa, Zaporizhzhya, and Kharkiv. These regions are considered important industrial centers in Ukraine and are densely populated. Covering the Ukrainian market from regional offices in Poland or Russia is not very effective. Ukrainian buyers are reluctant to go through regional offices, preferring to order direct for the manufacturer/seller. On-the-ground presence is very important to successful business development in Ukraine.

Joining the American Chamber of Commerce and obtaining experienced legal and accounting support are other important considerations when considering doing business in Ukraine.

While many U.S. firms have experienced marked success here, Ukraine is not a market for the first-time exporter. Companies doing business here must develop a tolerance for unpredictability and a long-term perspective to achieve success in business in Ukraine.

Current Market Trends

Healthcare funding in Ukraine is largely through taxation and healthcare services (ambulatory and hospital) are provided predominately by the public sector. Equipment used in public hospitals is typically obsolete and worn-out. Given the financial condition faced by many healthcare institutions, replacement of equipment is slow. The number of private clinics and practitioners is reporting steady growth.

A system of public healthcare insurance has been under discussion since at least 1996, but there has been no real action, nor a long-term policy implemented. Government health expenditures are very low, even by Eastern European standards: Ukraine spends around 7.0% of GDP on healthcare (one of the lowest levels in Europe). Due to a lack of funding, patients feel it is best to make under-the-table payments to guarantee quality care.

The Ukrainian market is open to advanced medical equipment, offering ease of use and cost savings. Receptivity to used medical equipment is average—on the one hand, there is a demand from end-users, but on the other hand, used equipment cannot be purchased through government tenders. However, a potential market for used medical equipment exists, with the preferred method being to assign a representative rather than distributors.

Main Competitors

Looking at the dynamics of foreign medical manufacturer penetration in the Ukrainian market, European and Japanese firms are more aggressive than their American competitors. They were the first to establish representative offices and focus on Ukraine as a potential market.

Domestic medical equipment production is not competitive on a global scale. Ukraine has some production capacity, but firms are generally under-capitalized and unable to compete with the high quality and relative low costs of imports.

Current Demand

- Diagnostic imaging equipment (ultrasound, computer tomography, magnetic-resonance tomography)
- Emergency medical equipment (ambulances, mobile hospitals)
- Operating rooms
- Telecommunication equipment for telemedicine
- Laser surgery devices
- Dental equipment and materials
- Laboratory equipment

The Ukrainian market is receptive to high-quality, advanced diagnostic and therapeutic equipment. Innovative technologies such as laser-optics in vascular surgery, urology, gastroenterology, dermatology and neurosurgery; and new diagnostic devices are becoming more popular. Modern equipment offering ease of use and cost savings is required in the fields of micro-surgery, radiology and bio-medicine.

Registration Process

Registration is a requirement for the importation of medical equipment into Ukraine. It is performed by the State Service for Medicinal Products and Medical Devices under the Ministry of Health (MoH), and is based on evaluation of the product by expert testing agencies. Applications for registration must be submitted (on a standard form) to the State Service. The State Service then refers to technical and clinical expertise performed by the expert organizations authorized by MoH. Based on technical and clinical expertise conclusions, the MoH issues the Registration Certificate.

Once registered, a product is included in the State registry of medical equipment and medical use products.

Registration is valid for five years. The procedure for renewal of registration follows the same procedure as registration.

Barriers

The registration of medical equipment can be a challenging and expensive process. It is best to become acquainted with the US Commercial Service to inform them of your plans to register your equipment and or products. They can inform the State Registry that the US Embassy is working with you and are available if there are any questions about the registration process. Medical equipment and devices (both locally manufactured and imported) can be used for medical practice in the territory of Ukraine only after being recorded in the State Register of Medical Equipment and Devices of Ukraine, and upon issuance of a registration certificate. Registration is performed by the State Service for Drugs and Medicinal Use Products.

According to current regulations, government tenders are to be non-discriminatory against foreign bidders, with some exceptions granted on a tender-by-tender basis. These exceptions give priority to domestic suppliers.

Trade Events

Public Health

October 23–26, 2012 • Kyiv • ***pe.com.ua/en/exhibitions/publichealth***
Medical equipment (dental, clinical laboratory and optical) and pharmaceuticals.

United Kingdom (UK)

Summary

The UK healthcare sector was worth $245 billion in 2011. It is split between the public healthcare system (National Health Service (NHS)), which was valued at just over $200 billion in 2011, and private healthcare ($45 billion). The NHS, which is publicly funded through taxation, provides free treatment at the point of delivery for the majority of its services. Despite cuts to the UK's public sector, healthcare spending is expected to remain steady. The private healthcare sector is mainly funded through private medical insurance. Its strengths lie in the provision of secondary and tertiary care, fields not traditionally offered by the NHS (for instance cosmetic surgery), or where public health services are limited (dental care). The nature of the UK healthcare market means that private sector growth is closely linked to public sector performance, policy and funding for core services.

The country's medical equipment market was valued at $8.4 billion in 2011. It is the world's sixth and Europe's third largest medical equipment market. The U.S. is the most important overseas source of medical devices, with an estimated 18% of share of the market in 2011. It is a leading supplier of diagnostic, dental, and orthopedic equipment and high quality wound care products to the UK. The pharmaceutical market was worth an estimated $37.3 billion in 2011. The Pharmaceutical Price Regulation Scheme (PPRS), which limits the profits companies are allow to make on their sales to the NHS, is expected to be replaced by some form of value-based pricing system in 2014.

Market Entry

The NHS is traditionally regarded as one system, and receives funding from central government, but is essentially managed as four separate segments: NHS Wales, NHS Scotland, HSC Northern Ireland and NHS England. NHS England, the largest segment (82% of the UK population), is comprised of regional trusts that have the choice of purchasing through organizations such as NHS Supply Chain (www.supplychain.nhs.uk), which maintains a product catalog of "approved" medical products and services. Trusts may also buy individually or pool resources with each other for procurement decisions. Companies developing or selling innovative products can approach organizations, such as the National Innovation Centre or NHS Innovations, for guidance. As there is very little opportunity to sell directly to the NHS from overseas, U.S. exporters are advised to form distribution partnerships with well-established local companies. This enables new entrants to take advantage of their partner's market expertise as well as their access to buyers and other decision makers within the NHS. Potential suppliers can approach private sector firms directly about procurement opportunities.

Statistics

Capital:	London
Population:	62.3 million (est. 2010)
GDP:	USD 2.3 trillion (est. 2011)
Currency:	Pound Sterling (£)
Language:	English

Contact

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Current Market Trends

- The UK's aging population is causing an increase in age-related health problems and demand for adequate social care. One way the NHS is seeking to address this is through the use of assistive technology which enables patients to self monitor their health. The growing use of home technology is part of a trend towards a shift in healthcare provision from hospitals to community services, and the wider use of e-health technologies.
- Demand exists within the rehabilitation and orthopedic area due to government efforts to promote disabled and elderly independence.
- There continues to be a focus on preventative care, in areas such as oral health, diet and fitness, to address the rise in 'lifestyle related' conditions such as diabetes and obesity.
- Within the dental market the private sector should continue to benefit from the shift of patients from the public sector to private providers. This is because the NHS limits the treatments it offers, while the private sector is able to offer more aesthetic and innovative treatments that patients are willing to pay for.
- Recent healthcare reform in England is creating opportunities for private sector health providers to supply more goods and services.
- Government use and support of generic drugs should help drive this segment.

Main Competitors

Many of the leading U.S. medical device and pharmaceutical manufacturers have subsidiaries in the UK. They include companies such as Abbott Laboratories Ltd, Johnson & Johnson Medical Ltd, Medtronic, GE Healthcare Ltd., GlaxoSmithKline PLC, and Pfizer Ltd. The UK medical device industry is still fragmented with many small companies selling specialist equipment and devices.

Current Demand

The Department of Health is currently committing substantial resources in treating:

- Cancer
- Alzheimer's Disease
- Parkinson's Disease
- Diabetes
- Rheumatoid Arthritis
- Digestive Disorders
- Communicable Diseases
- Obesity

Registration Process

Medical devices and medicines require an appropriate CE mark or marketing license, respectively, to be sold and marketed in the UK. The Medicines and Healthcare Products Regulatory Agency (MHRA), an agency of the Department of Health, governs the regulation of medicines and devices. For additional information please refer to: www.mhra.gov.uk

Barriers

U.S. companies should not encounter any political or trade barriers to market entry. The UK adheres to EU procurement rules and conducts most buying through commercial negotiation. That said, the NHS faces considerable financial pressure and so will often make purchasing decisions based on price alone, rather than factoring in quality or patient outcomes.

One hurdle that companies can face is the UK National Institute of Health and Clinical Excellence (NICE), which judges the clinical and cost-effectiveness of new and existing drugs, treatments, and medical devices. It provides the NHS with guidance on treatment strategy and influences procurement decisions by stating which products are reimbursable on the NHS.

Trade Events

Naidex Care, Naidex South, Naidex National, and Naidex Scotland

Multiple dates • London, Birmingham, & Glasgow • ***naidex.co.uk***

Home, disability and rehabilitation exhibitions.

Medical Device Technology Exhibition (MEDTEC)

May 2013 • Olympia & London • ***medtecukshow.com***

Exhibition for the medical devices manufacturing industry.

Pharmacy Show

September–October 2013 • Birmingham • ***thepharmacyshow.co.uk***

Pharmacy products, technology, solutions, and services.

Available Market Research

Please visit ***export.gov*** for the latest market research.

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Resources

export.gov
Locate your local CS office and find information about our international business services. Learn about export basics, including identifying your market, developing an export plan, conducting market research, and more.

CS Global Healthcare Team: *export.gov/industry/health*
Information on industry-specific trade events, trade leads, newsletters, and more.

Trade Finance Guide: *trade.gov/media/publications/pdf/tfg2008.pdf*
A quick reference for U.S. exporters, 2008 edition. Offers the basics of numerous financing techniques, from open accounts, to forfeiting, to government.

A Basic Guide to Exporting: *export.gov/basicguide*
First published in 1938, the recently-revised *Basic Guide* is designed to help U.S. businesses, especially small and medium-sized enterprises, face the challenges of today's global economy.

Free Trade Agreements: *export.gov/fta*
Learn how Free Trade Agreements can help make exporting easier for you.

AdvaMed
Advanced Medical Technology Association

The Advanced Medical Technology Association (AdvaMed) is the world's largest trade association representing medical device and diagnostics manufacturers. AdvaMed's member companies produce the innovations that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed has more than 400 member companies, ranging from the largest to the smallest medical technology innovators and manufacturers. AdvaMed advocates for a legal, regulatory, and economic environment that advances global health care by assuring worldwide patient access to the benefits of medical technology. The Association promotes policies that foster the highest ethical standards, rapid product approvals, appropriate reimbursement, and access to international markets.

DESH INTERNATIONAL
LAW

At Desh International, we help clients navigate the global marketplace. From personalized trade assessments to representing clients during international arbitration, we provide services for businesses engaged in a variety of international transactions and business ventures. Desh International advocates clients' interests in international negotiations when trade policy is formed, and helps clients enter new markets. As an international law firm, our goal is to help not only local communities, but also communities abroad. Economic growth and development often result from business collaboration and trade between countries; we seek to expand opportunity for people worldwide by actively participating in the liberalization of international markets and by helping businesses succeed in the global marketplace.

Certification Reference Chart

	Requires FDA Certification	Accepts FDA Certification	Requires CE Mark Certification	Accepts CE Certification	Other Certifications Required	Other Certifications Accepted	Certifying Body	Perferred Certified
Europe								
Austria	No	No	Yes	Yes	No	No	tuev.at	CE
Belgium	No	No	Yes	Yes	Yes	Yes	fagg-afmps.be	Yes
Bulgaria	No		Yes	Yes	GMP	ISO 9001; ISO 13485; ISO 13795	bda.bg	Yes
Czech Republic	No	No	Yes	Yes	Yes	Yes	Yes	Yes
Denmark	No	No	Yes	Yes	No	No	Dansk Standard	Yes
France	No	No	Yes	Yes	Depending on product Caution principle from the French Ministry of Health			
Germany	No	No[1]	Yes	Yes	Depending on product, X-ray ordinance; recycling ordinance, WEEE and RoHs.	N/A	EU Notified Bodies	N/A
Greece	No	No	Yes	Yes	Yes, for high-risk products, from the relevant authorities	No	EOF, ELOT, EKEVYL	YES
Ireland	No	Yes[2]	Yes	Yes	EU Directives: 90/385/EEC, 93/42/EEC, 98/79/EC	N/A	Irish Medicines Board	n/a
Italy	No	No	Yes	No	Italian Ministry of Health	N/A	Yes	CE certification
Netherlands	No	No	Yes	Yes	No	No		
Norway	No	No	Yes	Yes	No	No	Nemko, Justervesenet, Nordic Dental, DnV	
Poland			Yes	Yes	Class IIb and Class III products are required to obtain registration with the Office for Registration of Medical Products (URP)		URPL, PCBC	
Portugal	No	No	Yes	Yes	No	No	N/A	CE
Russia	No	No	No	No	Registration certificate from Ministry of Health	No	Ministry of Health	N/A
Slovakia	No	Yes	Yes	Yes	Yes	Yes	State Institute For Drug Control	Yes
Serbia	No	No	Yes	Yes	Depending on products, either Min. of Health or Min. of Environmental Protection regarding medical waste treatment	ISO 9001; ISO 13485; ISO 13795	Medicines and Medical Devices Agency of Serbia (ALIMS)	
Spain			Yes	Yes	Depending on product			
Sweden	No	No	Yes	Yes	No	No	lakemedelsverket.se	
United Kingdom	No	No	Yes	Yes	No	No	mhra.gov.uk	
Ukraine	No	No	No	No	Registration within the Ministry of Health	No	State Service for Medicinal Products and Medical Devices under the Ministry of Health of Ukraine	
Western Hemisphere								
Argentina	Yes				ANMAT		ANMAT	FDA
Brazil	Yes	Yes	Recommended	Yes	Registration/electric certification	Registration/ electric certification	Anvisa/Inmetro	Anvisa/Inmetro
Chile	No[3]	No[3]	No[3]	No[3]	No	No	Instutue of Public Health	FDA, CE
Dominican Republic	No	Yes	No	Yes	No	Yes	N/A	N/A
Mexico	Yes	Yes[4]	No	No	Technical Standards	No	COFEPRIS	COFEPRIS

	Requires FDA Certification	Accepts FDA Certification	Requires CE Mark Certification	Accepts CE Certification	Other Certifications Required	Other Certifications Accepted	Certifying Body	Perferred Certified
Middle East/Africa								
Egypt	Yes	Yes	Yes	Yes	ISO	ISO	MOH	MOH
Israel	Yes	Yes	Optional	Yes	Electricity Safety Testing	Australia and Japan Ministry of Health Approvals	Ministry of Health	
Jordan	Yes	Yes	Yes	Yes	Jordan Food and Drug Administration			
Kenya		Yes[2]		Yes[2]	Registration with the Pharmacy and Poisons Board (PPB) required for all pharmaceuticals.		PPB	
Nigeria	Yes	Yes	Yes	Yes	SONCAP (equipment); NAFDAC (food/drugs)			
Asia/Southeast Asia								
Australia	No	No	No[2]	Yes	TGA certification required in some instances.		Therapeutic Goods Administration	
China	Yes	No	No	No	No	No	SFDA	FDA
India	Yes	Yes	Yes	Yes	No	N/A	Central Drug Standard Control Organization (CDSCO)	N/A
Indonesia	Yes	Yes	No	Yes	Letter of Authorization from Principal; Certificate of Free Sales; Certificate of Analysis		ISO 13485; ISO 9001/CE/FDA/TUV; IEC 60601 (for electromedical)	FDA
Japan	No	No	No	No	N/A	N/A	Ministry of Health, Labour and Welfare (MHLW), Third Party Certification Bodies for devices with certification standards	N/A
Korea (South)	No	No	No	No				
Philippines	No	Yes[2]	Yes	Yes[5]	Legislation is pending.		The Philippine Food and Drugs Administration and the Center for Device Regulation, Radiation Health and Research	
Singapore	No	Yes	No	Yes	Needs some form of approved certification	MLHW (Japan), TGA (Australia), MDB (Canada)	Health Sciences Authority, Singapore	Yes
Taiwan	Yes	No	Yes	No	Yes	N/A	Yes	

1 FDA certification will assist with CE marking.7

2 Does not guarantee approval, but can be submitted during registration.

3 Although certification is not required, products without certification have very limited opportunities in this market.

4 Not automatically.

5 International medical equipment standards are accepted.

Subsector Reference Chart

Rating Definitions

1 Little to no probability of success for U.S. exporters

2 More challenges than opportunities

3 More oportunities than challenges

4 Very high probability of success for U.S. exporters

	Medical Devices	Medical Devices—Monitoring Equipment	Medical Devices—Orthopedic	Medical Devices—Surgical	Medical Capital Equipment	Bio Medical	Clinical Chemistry and Diagnostics	Dental	Dietary Supplements	Drugs & Pharmaceutical	Health IT	Laboratory Equipment	Used/Equipment	Veterinary	Consulting Services
Europe															
Austria	4	4	2	4	3	4	4	3	2	4	3	4	1	4	2
Belgium	3	2	2	3	3	3	3	3	2	2	2	2	1	2	1
Bulgaria	3	3	2	3	2	3	3	3	3	4	4	2	3	3	2
Czech Republic	3	3	3	3	2	3	3	3	2	3	3	3	2	3	2
Denmark	4	3	4	4	2	4	3	3	1	3	4	3	2	3	2
France	3	2	2	3	2	2	3	2	2	3	3	3	1	2	2
Germany	3	2	3	3	2	3	3	3	2	2	3	3	2	3	3
Greece	3	2	3	3	2	2	3	3	3	3	3	2	1	2	3
Ireland	3	2	2	3	2	3	2	2	3	3	3	2	2	3	3
Italy	3	3	2	3	2	3	3	3	2	2	4	3	2	2	2
Netherlands	3	3	3	3	2	3	3	2	2	2	4	3	1	3	2
Norway	3	2	2	3	2	3	3	3	2	2	3	2	1	3	3
Poland	2	2	2	2	1	2	2	3	2	2	2	2	2	2	2
Portugal	3	3	3	3	3	3	3	3	3	3	4	3	2	3	3
Romania	4	4	4	4	2	2	4	4	2	2	4	4	2	2	
Russia	4	4	3	4	3	4	4	3	1	2	2	3	1	2	1
Serbia	3	3	2	3	2	3	3	3	3	4	4	2	3	3	2
Slovak Republic	3	3	2	3	2	3	3	3	2	3	4	3	2	2	2
Spain	2	2	2	2	2	2	2	2	2	2	2	2	1	2	1
Sweden	3	3	2	3	2	3	3	3	2	3	4	3	1	2	2
United Kingdom	3	3	3	2	3	3	3	3	2	3	3	2	2	3	3
Ukraine	2	3	2	3	3	2	3	3	2	3	3	3	2	2	1
Western Hemisphere															
Argentina	3	3	3	3	3	3	3	3	2	3	3	3	2	3	3
Brazil	3	2	2	3	3	3	3	2	3	2	3	3	1	2	2
Chile	3	3	3	3	3	2	2	2	2	2	3	3	2	2	2
Dominican Republic	3	4	4	3	3	2	3	3	3	2	3	3	2	3	2
Guatemala	4	3	3	3	2	3	4	3	3	4	3	4	2	3	4
Mexico	3	4	4	4	3	3	3	4	2	3	4	3	4	4	3

Rating Definitions **1** Little to no probability of success for U.S. exporters **2** More challenges than opportunities **3** More oportunities than challenges **4** Very high probability of success for U.S. exporters	Medical Devices	Medical Devices—Monitoring Equipment	Medical Devices—Orthopedic	Medical Devices—Surgical	Medical Capital Equipment	Bio Medical	Clinical Chemistry and Diagnostics	Dental	Dietary Supplements	Drugs & Pharmaceutical	Health IT	Laboratory Equipment	Used/Equipment	Veterinary	Consulting Services
Middle East/Africa															
Egypt	3	3	3	4	2	3	3	3	3	3	2	3	1	3	2
Israel	3	3	3	3	3	3	3	3	2	3	4	3	1	3	1
Kenya	3	3	3	3	3	3	3	3	2	3	3	3	4	2	2
Nigeria															
Asia/Southeast Asia															
Australia	4	4	4	4	4	4	4	4	2	3	3	4	1	4	2
China	3	2	3	3	2	3	3	3	2	2	3	3	1	4	2
India	4	3	4	4	4	3	4	3	3	3	3	3	3	3	2
Indonesia	3	4	3	3	3	3	3	3	3	2	3	3	1	2	2
Japan	3	2	3	3	2	3	2	2	2	3	3	3	1	2	2
Korea (South)	3	2	3	3	2	2	2	3	3	2	2	2	1	2	1
New Zealand	3	2	2	3	2	3	2	2	3	2	3	3	1	3	3
Philippines	3	3	3	3	2	3	3	1	1	2	3	3	3	2	1
Singapore	2	3	3	2	3	3	3	2	3	2	3	3	1	2	2
Taiwan	4	4	4	4	3	4	4	3	3	3	4	4	1	3	3
Turkey	3	2	3	3	2	3	4	3	2	3	3	4	2	3	2

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